UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA; STATE OF CALIFORNIA; STATE OF GEORGIA; COMMONWEALTH OF MASSACHUSETTS ex rel. STF, LLC, an organization,

Plaintiffs,

v.

TRUE HEALTH DIAGNOSTICS, LLC, a Texas corporation; CHRIS GROTTENTHALER, CEO & FOUNDER, an individual; CAROL NELLIS, an individual; KEVIN CARRIER, d/b/a MRT HEALTH CONSULTANTS LLC, an Alabama limited liability corporation; SAM FILLINGANE, DO, an individual; JEFFREY "BOOMER" CORNWELL, an individual; CHARLES MAIMONE, an individual,

Defendants.

CASE NO. CV15-08251-CAS(JEMx)

COMPLAINT FOR MONEY DAMAGES AND CIVIL PENALTIES FOR VIOLATIONS OF THE FALSE CLAIMS ACT

DEMAND FOR JURY TRIAL

[FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)]

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Plaintiffs UNITED STATES OF AMERICA ("United States"), STATE OF CALIFORNIA ("California"), STATE OF GEORGIA ("Georgia"), and COMMONWEALTH OF MASSACHUSETTS ("Massachusetts") by and through Relator STF, LLC, allege as follows:

I. INTRODUCTION

1. Over the past several years, TRUE HEALTH DIAGNOSTICS, LLC ("TRUE HEALTH"), and its owners, executives, and board members (collectively, "Defendants"), have perpetrated a multi-million dollar fraud on U.S. taxpayers through various schemes designed to defraud Medicare, Medicaid, and private insurers.

2. Defendants provide illegal kickbacks in several forms to doctors and clinics, to induce those doctors and clinics to refer Medicare, Medicaid, and private insurance business to them. The kickbacks take the following forms, as described in detail in this Complaint:

a. Defendants promise doctors they will never collect co-payments or patient deductible payments from the doctors' patients. This is of great benefit to the doctors, who are able to attract and retain patients' business by promising no co-payments or patient deductible payments. In exchange for this benefit, the doctors order large Cardiovascular Disease ("CVD") test panels from Defendants, including panels for Medicare beneficiaries. The large CVD test panels are designed by TRUE HEALTH. As such, the waiver of deductibles and co-payments constitutes illegal remuneration, designed by Defendants to "pull-through" higher-paying Medicare and other business to Defendants. Defendants tell physicians that they should order these large panels because their patients will never have to pay anything. Furthermore, waiving insurance deductible and co-payments is explicitly illegal under the laws of several states. These large panels are ordered as often

as four times a year and are among the most expensive test panels ever designed.

b. Defendants pay doctors inflated monthly "consulting" fees for discussing test results over the phone. The fees Defendants pay far exceed the fair market value of the consultations, and constitute illegal remuneration designed to induce the referral of Medicare, Medicaid, and other business.

c. Defendants contract with a sales force of independent contractors who are paid predominantly on commissions based on referrals of patients and are highly incentivized to increase referral business. Defendants enter into sales agreements to pay these independent contractors a commission based on a percentage of the laboratory's revenue in exchange for the contractor arranging for and recommending physicians who order tests that are reimbursed by federal programs. Anti-kickback statutes prohibit entities and individuals from receiving remuneration in return for "arranging for" or "recommending" the purchase or order of a "good" or "service" reimbursed by federal health programs. 42 U.S.C. §1320a-7b(b)(1)(B). The anti-kickback statutes likewise prohibit laboratories from paying such remuneration. *Id.*

d. Defendants pay doctors to be members of their "Speakers Bureau," in exchange for the doctors' referral of all CVD panels – including panels for Medicare and Medicaid beneficiaries – to Defendants.

3. These practices constitute illegal kickback schemes, no more legal than if Defendants simply handed doctors envelopes of cash in exchange for Medicare, Medicaid, and other referrals.

4. Additionally, Defendants systematically bill Medicare, Medicaid, and other payors for medically unnecessary tests. Specifically, Defendants' test bundles ("panels") include tests that are pre-selected by Defendants as part of their panels;

TRUE HEALTH sales representatives encourage doctors not to de-select any of the tests. Because TRUE HEALTH does not bill patients for co-pays or deductibles, the physicians have no incentive to de-select any of the tests. Because there is no cost to their patients, TRUE HEALTH's physician clients order TRUE HEALTH's test panels indiscriminately for the vast majority of their patients without any thought or consideration of medical necessity. Knowing this, TRUE HEALTH has designed its test panels to maximize reimbursement from Medicare and other payors. Defendants then perform and bill Medicare and other payors for each of the tests. Each time they do so, Defendants violate the Federal False Claims Act and the Georgia, and Massachusetts' false claims acts.

5. Defendant TRUE HEALTH recently acquired Health Diagnostic Laboratory, Inc. ("HDL"). By acquiring HDL, TRUE HEALTH has increased its Medicare, Medicaid, and private insurance business significantly, thereby increasing the magnitude of its fraudulent practices.

6. A member of Relator recently received an email from a California physician confirming that TRUE HEALTH perpetrates the fraudulent schemes alleged above.

7. In the email (attached hereto as Exhibit 1) the physician explains that a TRUE HEALTH representative she recently spoke with confirmed: (1) TRUE HEALTH requires that physicians use the large test panels, which consist of medically unnecessary lab tests; (2) these large panels should be run every three months if any of the patient's initial tests establish any abnormalities; (3) about 95% of TRUE HEALTH's client physicians utilize these medically unnecessary panels; (4) TRUE HEALTH will not charge privately insured patients co-pays or deductibles; (5) TRUE HEALTH will use their client physicians' phlebotomists to draw blood, treating them as independent contractors and paying them $15 per blood draw; (6) TRUE HEALTH directs its physician clients to have their phlebotomists' "clock-out" while they draw blood for TRUE HEALTH submissions, and

encourages the physicians to reduce the phlebotomists salaries by the amount TRUE HEALTH pays the phlebotomists for blood draws; and (7) TRUE HEALTH would provide a free health coach to work with physicians' patients.

8. TRUE HEALTH's CEO, CHRIS GROTTENTHALER, recently issued a letter to physicians assuring them that TRUE HEALTH's acquisition of HDL would not disrupt the flow of kickbacks from TRUE HEALTH to its physician clientele. Specifically, Defendant Grottenhaler assured TRUE HEALTH's clients that things would continue to be "**business as usual.**" (See September 30, 2015 letter from CHRIS GROTTENHALER to Providers, attached hereto as Exhibit 2). Defendant Grottenthaler has made it clear that TRUE HEALTH is intent on defrauding Medicare and other payors through the various schemes noted above and described in the physician email attached hereto as Exhibit 1.

9. Additionally, despite certifying compliance with various federal statutes, Defendants have knowingly misrepresented their laboratory's operations. Defendants "sent out" more than 30% of their tests to other laboratories, yet billed Medicare as if they had processed the tests themselves. This is illegal.

10. These schemes violate not only Medicare regulations, but also state Medicaid and insurance regulations. The fraudulent intent of these schemes is exacerbated by Defendants knowingly charging state Medicaid programs at rates far in excess of their lowest charges. Defendant TRUE HEALTH charges various state Medicaid programs as much as 100% more for lab tests than it does its private insurers. As shown in Exhibits 3 and 4, a survey of billing for 29 TRUE HEALTH tests, which amounts to 31% of TRUE HEALTH's 85 test Baseline Panel, shows that on average Defendants overcharged Medicaid programs in Georgia by 62%, and Massachusetts by 51% (See Medicaid Lowest Charge charts, attached hereto as Exhibits 3, and 4 respectively).

11. TRUE HEALTH's schemes have allowed it to secure substantial Medicare and other business in a short period of time. TRUE HEALTH's success

would be unattainable without its fraudulent schemes because TRUE HEALTH has zero proprietary or otherwise unique testing to offer.

12. Medicare is administered by the United States government, and provides health coverage to people 65 years of age and older. Medicare's soaring costs are staggering. In 2014, Medicare expenditures accounted for $511 billion of federal spending. Knowing that the federal Government lacks the ability to track the massive amount of Medicare money as it flows through the complex healthcare delivery system, unscrupulous companies see government money as an easy source for padding their profits. Sadly, Defendants have become part of this problem through their abuse of the Medicare program – a program designed to benefit senior citizens, not private companies.

13. Title XIX of the Social Security Act and Title 42 of the Code of Federal Regulations authorize individual states to develop and manage their own Medicaid programs. Medicaid is a joint federal-state program that provides health care benefits, including laboratory services coverage, for certain groups including the poor and disabled. The funding for Medicaid is shared between the federal and state governments. Each state is required to implement a state plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. *Id.* The federal portion of each state's Medicaid payments, known as the Federal Medicaid Assistance Percentage is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d (b).

14. In addition to the Medicaid statutes, many states also have their own false claims statutes, which mirror the federal FCA. Defendants' schemes violate these state statutes as well. These violations are even more egregious because they have been accomplished through knowing violations of the long-established federal anti-kickback laws.

15. In engaging in these illegal practices, Defendants are not only cheating the system, but also driving competitors out of the marketplace, thereby reducing the quantity and quality of treatment options for the poor, the elderly, and the disabled.

16. This is a *qui tam* action for violation of the federal False Claims Act (31 U.S.C. §§ 3150 *et seq.*) and the false claims acts of Georgia and Massachusetts to recover treble damages, civil penalties and attorneys' fees and costs for Plaintiffs and on behalf of the United States, Georgia, and Massachusetts for fraudulent Medicare and Medicaid billings. Non-public information personally known to Relator STF, LLC ("STF") serves as the basis for this action. Some of Defendants' schemes have also caused private insurers in California to be overcharged. Accordingly, Relator brings claims under California Insurance Code §1871.7, *et seq.*, to recover fraudulent charges on behalf of the California Department of Insurance.

II. JURISDICTION AND VENUE

17. This Court has jurisdiction over this action pursuant to 31 U.S.C. sections 3730(b) and 3732(a), which confer jurisdiction on this Court for actions brought under the federal False Claims Act, and authorize nationwide service of process. Venue is proper in this district pursuant to 31 U.S.C. section 3732(a), as all Defendants transact business in the Central District of California.

III. PARTIES

18. The plaintiffs in this action are the UNITED STATES OF AMERICA ("United States"), the STATE OF CALIFORNIA ("California"), the STATE OF GEORGIA ("Georgia"), and the COMMONWEALTH OF MASSACHUSETTS ("Massachusetts") by and through Relator STF, LLC.

19. Relator STF, LLC is a limited liability company, whose members are involved in the laboratory industry.

20. Defendant TRUE HEALTH DIAGNOSTICS, LLC ("TRUE HEALTH"), is a Texas limited liability company with its principal place of business

in Frisco, TX. In September 2015, TRUE HEALTH bought Health Diagnostics Laboratory, Inc. (""HDL"), a Richmond, Virginia-based company, through a bankruptcy proceeding.

21. Defendant CHRIS GROTTENTHALER is CEO and founder of Defendant TRUE HEALTH. This is not the first time Defendant Grottenhaler has been connected to an illegal scheme to bribe physicians for the purpose of capturing Medicare business. Defendant Grottenhaler was previously VP of Finance at Ameritox. During Defendant Grottenhaler's tenure at Amertiox, the Department of Health and Human Services accused the company of paying kickbacks to induce its physician clientele to refer drug testing services to the lab that were reimbursable by Medicare. In 2010 Ameritox paid $16.3 million to settle the case. TRUE HEALTH's business model is essentially the same as Ameritox's fraudulent business model: pay physicians cash to induce Medicare referrals. At Defendant Grottenhaler's direction, however, TRUE HEALTH adds a new twist. TRUE HEALTH pays physicians' phlebotomists at above market rates for blood draws that are submitted to TRUE HEALTH for test panels. The additional income the physicians' phlebotomists generate from TRUE HEALTH allows physicians to reduce their phlebotomists' salaries, thereby increasing the physicians' profits. TRUE HEALTH does this to induce Medicare referrals.

22. Defendant CAROL NELLIS is Senior Vice President of Sales and Marketing at TRUE HEALTH. Defendant Nellis worked with Defendant Grottenhaler at Ameritox during the fraud described above. During a conference in Miami, Defendant Nellis and Defendant KEVIN CARRIER personally assured a physician that TRUE HEALTH would not charge her patients co-pays or deductibles. Specifically, Defendants Nellis and Carrier assured the physician that she "should not worry as they (TRUE HEALTH) never actually required that patients pay anything. [She] therefore would not be concerned about the cost to patients." (See 9-22-15 email attached hereto as Exhibit 5).

23. Defendant SAM FILLINGANE, D.O., is Chair and Director of Medical Education at TRUE HEALTH. Defendant Fillingane leads TRUE HEALTH's kickback scheme for Medicare referrals by dispensing cash to physician clients for a monthly phone conversation with him. Defendant Fillingane was previously the highest paid physician on HDL's list of doctors receiving money from Medicare as a result of referring business to HDL. Defendant Fillingane refers a considerable amount of Medicare, Medicaid, and other government funded healthcare business to TRUE HEALTH. TRUE HEALTH pays Defendant Fillingane to influence other physicians to refer Medicare, Medicaid, and other government funded healthcare business to TRUE HEALTH.

24. Defendant KEVIN CARRIER, through his wholly owned LLC, MRT HEALTH CONSULTANTS, became a contract sales representative for TRUE HEALTH in 2014. On May 10, 2015, Defendant Carrier sent an email to the physician mentioned above, stating the following:

> True Health Diagnostics is a value based lab, meaning we intend to deliver ninety-five percent of the clinical value at half-costs. Our intention at True Health Diagnostics is to protect the provider and the patient by delivering high value testing while at the same time minimizing, if not eliminating unnecessary investigational testing. We believe by doing this we can provide a high level of care to the patient without exposing the patient to unreasonable bills nor exposing the provider to extensive scrutiny by payors.

(See 5-10-15 email, attached hereto as Exhibit 5). These assurances were patently false. First, TRUE HEALTH does not provide CVD test panels at half cost. Instead, the TRUE HEALTH Baseline Panel has 85 tests at a Medicare cost of at least $2,000. Second, the TRUE HEALTH Baseline Panel has at least eight tests that the FDA has not approved. Defendant Carrier, along with Defendant Nellis, told that same physician during a meeting in Miami that the physician "should not worry as they (True Health) never actually required that patients pay anything." (9-22-15 email attached hereto as Exhibit 5).

25. Defendant JEFFREY P. "BOOMER" CORNWELL is a sales representative for Defendant TRUE HEALTH. Defendant Cornwell is based in Texas. Defendant Cornwell was previously a contract sales representative for Blue Wave.

26. Defendant CHARLES MAIMONE is a contract sales representative for Defendant TRUE HEALTH. Defendant Maimone is based in New Jersey. Defendant Maimone was previously a contract sales representative for Blue Wave.

27. Other shareholders, officers, and board members of Defendants controlled and profited from the schemes alleged herein, and this complaint will be amended with their names once they are known.

IV. OVERVIEW OF THE SCHEME

28. TRUE HEALTH is a commercial reference laboratory. Commercial reference laboratories perform clinical laboratory services, which entail analyses of human body specimens, including blood, to assist physicians in diagnosing human disease and monitoring treatment. TRUE HEALTH performs clinical laboratory services for patients covered under the federal Medicare program, state Medicaid programs, and private managed care companies. Commercial reference laboratories, like TRUE HEALTH, obtain requests for clinical tests from physicians, clinics, and hospitals. When the laboratories run these tests, they submit claims for reimbursement to the appropriate payer – Medicare, Medicaid, or private insurance – for reimbursement, identifying the tests performed by a uniform Current Procedure Technology ("CPT") code. These claims are typically submitted electronically to government and private payors such as Aetna, Cigna, Blue Cross/Blue Shield, and United Healthcare.

29. As a condition of receiving payment from Medicare and Medicaid, TRUE HEALTH certified, both implicitly and explicitly, its compliance with relevant federal and state statutes and regulations, as more fully described herein. Rather than abide by these statutes and regulations, Defendants defrauded these

programs, induced physicians to order tests by offering kickbacks, and submitted claims for medically unnecessary tests.

30. Despite certifying compliance with relevant Medicare statutes, Defendants have misrepresented their laboratory operations, in violation of federal statutes. Specifically, Defendants have "sent out" more than 30 percent of their lab tests to other laboratories. Defendants need to do this because they have not had the capabilities, equipment, or staff to perform the tests they offer. Nonetheless, Defendants falsely certify that the tests were performed at their laboratory in order to submit claims to Medicare. In violation of express CLIA requirements, Defendants also omit, from their test reports, the identity of the lab that actually performed the tests.

31. In order to capture and retain Medicare and Medicaid business, Defendants also offer several forms of illegal remuneration to physician customers in order to induce referral of Medicare and Medicaid business.

32. First, Defendants waive patients' private insurance deductible payments. Most private insurance companies require that a patient ordering a laboratory test make a deductible payment to the laboratory until the patient has met his or her deductible amount each year. The deductible payments can be significant to patients. For example, for a TRUE HEALTH Baseline Panel, the deductible payment, if charged, could be more than $2,000. Accordingly, the waiver of a deductible payment is a significant benefit that a physician can provide to his or her patients. Knowing this, Defendants promise physicians that they will not collect deductible payments, as long as the physicians send all of their CVD-related business—including Medicare and Medicaid business—to Defendants' laboratories.

33. Defendants also waive patients' private insurance co-payments. A significant portion of a physician's non-Medicare patients will be covered by private insurance. Most private insurance companies require that a patient ordering a laboratory test make a co-payment of approximately 20 percent of allowable charges

to the laboratory. The co-payments can be significant to patients, especially those being treated with satin therapy, who require regular medical treatment and lipid testing with attendant co-payments at least four times per year. For example, in the case of the TRUE HEALTH Baseline panel, the co-payment, if charged, could be at least $400. Accordingly, the waiver of a co-payment is a significant benefit that a physician can provide to his or her patients. Knowing this, Defendants promise physicians that they will not collect co-payments, as long as the physicians send all of their CVD-related business—including Medicare and Medicaid business—to Defendants' laboratories.

34. Though Defendants lose money on uncollected co-payments and deductibles, they more than make up the difference with the profits they earn on the Medicare and Medicaid referral business. This Medicare and Medicaid business, induced by the deductible and co-payment waiver for privately insured patients, is referred to in the industry as "pull-through" business. The majority of Medicare patients are receiving statin therapy, and therefore receive lipid testing four times per year. This amounts to annual Medicare payments of over $8,000 per patient.

35. Waiving co-payments and deductibles in this manner, to induce the referral of pull-through Medicare and Medicaid business constitutes illegal inducement, strictly prohibited by the anti-kickback laws.

36. The second form of illegal remuneration Defendants provide to induce the referral of Medicare and Medicaid business is the payment to physicians of inflated "consulting" fees. When a physician orders a test for a patient, the laboratory can call and discuss the results of the tests with the physician. Defendants in this case pay physicians grossly inflated "consulting" fees for mere minutes of discussing lab results with the ordering physicians. These "consulting" fees are pure artifice, thinly disguised kickbacks. The former Blue Wave Sales Reps designed this scheme as a replacement for the bribes they previously paid for "packaging fees." The fees paid by Defendants far exceed the fair market value of

the physicians' time, and are intended as illegal remuneration to induce the referral of physicians' Medicare, Medicaid, and other business.

37. The third form of kickbacks Defendants pay are "speaking fees" paid to physicians who sign up to be part of Defendants' "Speakers Bureau." In exchange for speaking at conferences once or twice a year, if at all, and/or local dinners and round tables, Defendants pay these referring physicians thousands of dollars. Again, the fees Defendants pay far exceed the fair market value of the physicians' speaking services, and are intended as illegal remuneration to induce the referral of the physicians' Medicare, Medicaid, and other business.

38. The fourth form of kickbacks is in Defendants' agreements with sales persons responsible for delivering TRUE HEALTH's test volume. Defendants enter into sales agreements whereby TRUE HEALTH pays contractors a commission based on a percentage of the laboratory's revenue in exchange for the contractor arranging for and recommending physicians who order tests that are reimbursed by federal programs. Anti-kickback statutes prohibit entities and individual s from receiving remuneration in return for "arranging for" or "recommending" the purchase or order of any "good" or "service" reimbursed by federal health programs. 42 U.S.C. §1320a-7b(b)(1)(B). The anti-kickback statutes likewise prohibit TRUE HEALTH from paying such remuneration. Id. Defendants negotiated and entered into these agreements, knowing they violated anti-kickback statutes and, therefore, submitted false claims.

39. In addition to providing illegal kickbacks, Defendants overcharge Medicare, Medicaid, and other government programs by systematically billing for medically unnecessary tests. As just one of many examples, two of TRUE HEALTH's test bundles ("panels") include both an Apo B test, and an LDL-P test. Both of these tests measure total LDL particles. There is no medical benefit to including both of these tests since they provide the same medical information and treatment would not be affected by including both tests. Defendants pre-select both

tests as part of their panels; doctors are encouraged not to de-select one of the tests. Defendants then perform, and bill Medicare, Medicaid, and other government programs for, each of the tests. Defendants charge Medicare, Medicaid, and other government programs in excess of $19.95 for the Apo B test, and $42.93 for the LDL-P test. Each time they do so, Defendants violate the False Claims Act.

V. DEFENDANTS KNOWINGLY VIOLATED THE FEDERAL FALSE CLAIMS ACT BY MISPREPRESENTING THEIR COMPLAINCE WITH BASIC LABORATORY OPERATIONS REGULATIONS.

A. Defendants outsource laboratory work in excess of the thirty percent permitted by the "shell laboratory provision" requirements

40. Defendants have knowingly violated the False Claims Act by referring more than 30 percent of their lab tests to one or more non-related laboratories (i.e., laboratories that Defendants do not wholly own) and then billing Medicare for those referred tests. Specifically, Social Security Act section 1833(h)(5)(A) provides that a referring laboratory may bill for clinical laboratory diagnostic tests on the clinical laboratory fee schedule for Medicare beneficiaries performed by a reference laboratory only if the referring laboratory does not, inter alia, refer more than 30 percent of the clinical laboratory tests for which it receives requests for testing during the year. Defendants have routinely referred more than 30 percent of their lab tests to non-related labs and then billed Medicare for those tests in violation of the False Claims Act.

B. Defendants knowingly misrepresent their laboratory's operations in order to bill Medicare for tests it does not perform

41. Defendants knowingly misrepresent to Medicare that they perform the majority of their tests in house. Federal law requires that lab test reports include information about the name and address of the laboratory performing the tests. 42 C.F.R. § 493.1291(c). As of at least August 2015, TRUE HEALTH did not have the capacity to perform the litany of tests included in its panels. TRUE HEALTH sent these tests out to other laboratories to perform or simply did not perform them at all.

Yet, TRUE HEALTH only lists its own laboratory on its "Laboratory Test Results Report." (See Exhibit 5).

42. Consequently, each test that TRUE HEALTH billed Medicare for but did not perform itself, and did not properly identify as a test performed by another laboratory, constitutes a violation of the False Claims Act.

VI. DEFENDANTS KNOWINGLY VIOLATED THE FEDERAL FALSE CLAIMS ACT THROUGH MULTIPLE ILLEGAL KICKBACK SCHEMES.

43. Defendants violated the False Claims Act by charging Medicare, Medicaid, and other government programs for lab tests that were referred to Defendants by providers because of kickbacks offered to those providers by Defendants. Defendants' practices are unlawful as kickback schemes, strictly prohibited by Medicare statutes. Specifically, 42 U.S.C. § 1320a-7b(b)(2)(A) prohibits "Illegal remunerations" for "[w]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) ***directly or indirectly, overtly or covertly***, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program . . . ." 42 U.S.C. § 1320a-7b(b)(2)(A) (emphasis added).

44. Interpretations of this language by the federal authorities provide useful guidance in applying these anti-kickback laws, and establish that Defendants have violated the anti-kickback laws of the United States through the conduct described herein. For example, the federal Department of Health and Human Services, Office of the Inspector General ("OIG"), reaffirmed on May 9, 2008, that: "[W]hen a laboratory offers or gives an item or service for free **or less than fair market value to a referral source, an inference arises that the item or service is offered to induce the referral of business**." OIG Advisory Opinion No. 08-06. An anti-kickback "violation arises if the discount whatever its size is **implicitly or explicitly**

tied to referrals of" government-funded business. OIG Opinion Letter, April 26, 2000.

45. In October 1994, the OIG issued a Special Fraud Alert, entitled "How Does the Anti-Kickback Statute Relate to Arrangement for the Provision of Clinical Lab Services?" As an example of a situation giving rise to an inference of an illegal kickback, the Special Fraud Alert cited laboratories that waive charges to providers for lab tests of managed care patients (such as the co-payments and deductibles of patients here).

46. Moreover, in June 2005, the OIG issued an Advisory Opinion concluding that payments by a laboratory to referring physicians of $6 per day for "collection of blood samples," likely constituted "prohibited remuneration under the anti-kickback statute." OIG Advisory Opinion No. 05-08, at pp. 1-2. Specifically, the OIG concluded that:

> **Where a laboratory pays a referring physician to perform blood draws, particularly where the amount paid is more than the laboratory receives in Medicare reimbursement, an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory . . . .**
>
> . . . . Because the physicians would receive a portion of the Lab's reimbursement for blood tests resulting from the physicians' referrals, **the physicians have a strong incentive to order more blood tests. As a result, there is a risk of overutilization and inappropriate higher costs to the Federal health care programs.**

Id. at p. 4.

47. More recently, the OIG issued and opinion stating that when a laboratory pays a referring physician for performing blood draws, and where the amount exceeds $3, "an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory." OIG Advisory Opinion No. 05-08, p. 4; *see also* OIG Special Fraud Alert: Laboratory Payments to Referring Physicians, p. 4, n.10 (June 2014).

48. Defendants violated the anti-kickback laws described in these OIG opinions by: (1) waiving co-payments and deductibles; (2) paying referring

physicians inflated "consulting fees"; (3) paying physicians' phlebotomists $15 for "collection of blood sample" and encouraging the physicians to reduce their phlebotomists salaries by having them clock-out to draw patient specimens for TRUE HEALTH thereby increasing the physicians' profit; (4) contracting with sales persons on a 1099 basis; and (5) paying sham "Speakers Bureau" fees to referring physicians. All of these kickback schemes are both implicitly and explicitly tied to the referral of Medicare, Medicaid, and other government healthcare business and therefore violate the anti-kickback laws described in the aforementioned OIG opinions. Defendants presented to Medicare, Medicaid, and other government programs claims for reimbursement of laboratory tests the referral of which was induced, in whole or in part, directly or indirectly, overtly or covertly, by the provision of the kickbacks described above. Each of those claims constitutes a violation of the False Claims Act.

49. At all times relevant hereto, Defendants knew that federal law prohibited their giving or receiving these kickbacks. Defendants certified, both explicitly and implicitly, that each claim they submitted to Medicare would fully comply with all statutes and regulations, including the anti-kickback provisions, and that as Medicare providers, they would comply with all pertinent statutes and regulations, including the anti-kickback provisions.

50. Each claim for payment that Defendants submitted to Medicare, Medicaid, and other government programs from at least 2014 to the present, that was referred to Defendants by a provider who received from Defendants any of the forms of remuneration described above constitutes a false claim in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq.* Over this time period, Defendants have submitted tens of thousands of such claims for payments, and received tens, if not hundreds, of millions of dollars from the Government as a result of these illegal kickbacks.

A. Defendants' waiver of patient co-pay and deductibles are illegal kickbacks

51. Defendants defrauded Medicare and private insurers by routinely waiving patients' deductibles or copays as incentive for physicians to refer business to TRUE HEALTH. TRUE HEALTH's Sales Representatives met with physicians and encouraged them to order panels for their non-Medicare and Medicare covered patients. In doing so, TRUE HEALTH promised to waive patients' private insurance co-payments and deductibles.

52. Typically, private insurance companies and some government healthcare programs require that a patient ordering a laboratory test make a co-payment of approximately 20% of allowable charges to the laboratory. Private insurance companies may also require their patients to make a deductible payment to the laboratory until the patient has met his/her deductible amount for the year. Although co-payments and deductibles can be a financial burden to patients, especially to those seeking treatment for coronary artery disease, service providers are required to make all necessary efforts to collect co-payments from patients, with limited exceptions.

53. Accordingly, waivers of insurance co-payments and deductibles are significant benefits that physicians can provide to their patients because they allow the patients free laboratory testing no matter how many tests are ordered. Physicians therefore market these waivers to their patients to make their offices more appealing, thereby improving the physicians' overall revenue and ratings. These waivers save physicians from having to deal with patients upset over large deductible payments and co-payments for questionable laboratory tests. Ultimately, this mutually beneficial kickback arrangement incentivizes physicians to indiscriminately order all available tests and to do so strictly from TRUE HEALTH.

54. Knowing this, Defendants promise physicians that it will not collect co-payments or deductibles. For example, as part of its sales pitch, Defendants' sales

representative in the Southeast told a physician that while TRUE HEALTH would bill private insurance companies and possible patients, TRUE HEALTH never required patients to pay. (See 9-22-15 email attached hereto as Exhibit 5). Defendant implicitly reiterated TRUE HEALTH'S co-pay and deductible waiver in a May 10, 2015 email to a physician stating: "[W]e can provide a high level of care to the patient without exposing the patient to unreasonable bills nor exposing the provider to extensive scrutiny by payors." (See Exhibit 5) (emphasis added). Defendants' message is clear: physicians can order any test they want – even medically unnecessary tests – because the costs are picked up by Medicare, Medicaid, other government programs, and insurance companies. Although TRUE HEALTH lost money on uncollected co-payments and deductibles, it more than made up the difference with the profits it earned on the referral business.

55. While TRUE HEALTH's written billing policy claims to make "reasonable attempts" to collect from patients, in reality no effort is actually made to collect from patients. In fact, Defendants' sales force, including specifically TRUE HEALTH's VP of Sales and Marketing, CAROL NELLIS, and TRUE HEALTH sales representatives JEFFREY P. "BOOMER" CORNWELL out of Texas, KEVIN CARRIER out of Alabama, and CHARLES MAIMONE out of New Jersey , guarantee physicians that their patients would not receive a bill for their tests.

56. Waiving co-payments and deductibles in this manner, to induce physicians to order tests, constitutes illegal inducement, strictly prohibited by anti-kickback laws. *See* 42 U.S.C. §1320a-7a. As discussed above, anti-kickback statutes prohibit the knowing and willful remuneration (including discounts) even if one purpose of the remuneration is to induce or reward referrals of Federal health care program business. By engaging in this unlawful conduct, TRUE HEALTH also encouraged the submission of medically unreasonable and unnecessary tests, thereby violating 42 U.S.C. 1395y(a)(1)(A). As such, each of these claims constitutes a false

claim in violation of the False Claims Act (31 U.S.C. § 3729 et seq.), and the California Insurance Code.

B. Defendants' inflated "consulting fees" are illegal kickbacks

57. Defendants induced the ordering of its tests – including tests ultimately billed to Medicare, Medicaid, and other government programs – by paying physicians significant amounts every month to review lab results over the phone. As a pretense, Defendants tell medical providers that the physician is providing "consulting services" to TRUE HEALTH.

58. In reality, Defendants' "consulting fees" are an unlawful kickback scheme, strictly prohibited by the Medicare statutes, and give rise to False Claims Act liability. The "consulting fees" paid by Defendants to referring providers in this case are no different from those proscribed by the OIG through its Advisory Opinions. Defendants' fees and other "compensation provides an obvious financial benefit to the referring physician, and it may be inferred that this benefit would be in exchange for referrals to the Lab." OIG Advisory Opinion No. 05-08, at p. 4. This alone gives rise to an inference of illegal remuneration.

59. Moreover, as in the scenario considered by the OIG's Advisory Opinion, the "consulting" fees and other remuneration provided by Defendants have the effect of incentivizing physicians to order more tests, creating a "risk of overutilization and inappropriate higher costs to the Federal health care programs." *See* OIG Advisory Opinion No. 05-08, p. 4.

60. Defendants presented to Medicare, Medicaid, and other government programs claims for reimbursement of laboratory tests which were neither reasonable nor necessary but were ordered by physicians in exchange for kickbacks. In doing so, Defendants caused thousands of submissions of reimbursement claims for laboratory tests that were not medically necessary. As such, each of these claims constitutes a false claim in violation of the False Claims Act (31 U.S.C. §§ 3729 *et seq.*). Defendants certified, both explicitly and implicitly, that each claim they

submitted to Medicare would fully comply with all statutes and regulations, and that as Medicare providers they would comply with all pertinent statutes and regulations.

C. Defendants' sham "Advisory Board" is an illegal kickback

61. Similar to Defendants' fraudulent "consulting fees" scheme, Defendants also fraudulently paid doctors who allegedly participated on their sham "Advisory Board." Defendants paid high volume physicians to move their business to TRUE HEALTH in exchange for an "advisor" fee. Defendant Dr. Sam Fillingane, TRUE HEALTH's Chair and Director of Medical Education, heads TRUE HEALTH's sham "Advisory Board." Dr. Fillingane moved his laboratory testing to TRUE HEALTH upon accepting this position. TRUE HEALTH's website makes only a passing reference to this Advisory Board, but no doctors are named.

62. Again, Defendants' practices are an unlawful kickback scheme, strictly prohibited by the Medicare statutes, and give rise to False Claims Act liability. The "advisor" fees paid by Defendants to referring providers in this case are no different from those proscribed by the OIG through its Advisory Opinions. Defendants' fees and other "compensation provides an obvious financial benefit to the referring physician, and it may be inferred that this benefit would be in exchange for referrals to the Lab." OIG Advisory Opinion No. 05-08, at p. 4.

63. Moreover, as in the scenario considered by the OIG's Advisory Opinion, the "consulting" and "advising" fees and other remuneration provided by Defendants have the effect of incentivizing physicians to order more tests, creating a "risk of overutilization and inappropriate higher costs to the Federal health care programs." *See* OIG Advisory Opinion No. 05-08, p. 4.

64. Defendants presented to Medicare, Medicaid, and other government programs claims for reimbursement of laboratory tests which were neither reasonable nor necessary but were ordered by physicians in exchange for kickbacks. In doing so, Defendants caused thousands of submissions of reimbursement claims for laboratory tests that were not medically necessary. As such, each of these claims

constitutes a false claim in violation of the False Claims Act (31 U.S.C. §§ 3729 *et seq.*). Defendants certified, both explicitly and implicitly, that each claim they submitted to Medicare would fully comply with all statutes and regulations, and that as Medicare providers they would comply with all pertinent statutes and regulations.

D. Defendants contract with sales persons to direct referrals in exchange for illegal remuneration

65. Defendants enter into illegal sales agreements to induce ordering of tests from TRUE HEALTH in exchange for a commission based on a percentage of the laboratory's revenues.

66. Anti-kickback statutes prohibit entities and individuals from receiving remuneration in return for "arranging for" or "recommending" the purchase or order of an "good" or "service" reimbursed by federal health programs. 42 U.S.C. § 1320a-7b(b)(1)(B). The anti-kickback statutes likewise prohibit TRUE HEALTH from paying such remuneration. Id. Claims that induce the ordering of items or services from a violation of the anti-kickback statutes are false or fraudulent under the federal False Claims Act. 42 U.S.C. § 1320a-7b(g).

67. The OIG's guidance on the issue of contracted and commission based laboratory sales forces is instructive. Specifically, the OIG has published safe harbor regulations that precisely define arrangements and conditions which are not subject to anti-kickback violations because they would be unlikely to result in fraud or abuse. *See* HHS-OIG Advisory Opinion NO. 05-08, Issued August 2005, available at http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao05_08.pdf; *see also* HHS-OIG Advisory Opinion NO. 99-3; *see also* HHS-OIG Advisory Opinion No. 98-10; see also HHS-OIG Advisory Opinion No. 10-23. Defendants' sales agreements do not meet these standards.

68. In the context of independent contractors, arrangements must meet seven standards, including setting forth in advance aggregate compensation based on fair market value and not determined in a manner that takes into account the volume

or value of any referral or business otherwise generated between the parties. 42 C.F.R. § 1001.952(d). Defendants' arrangements cannot qualify for this safe harbor because aggregate compensation is not set out in advance, the compensation paid exceeded fair market value, and the amount of compensation is directly tied to referrals between Defendants and other parties.

69. *Bona fide* employees are also covered by safe harbor provisions. 42 U.S.C. § 1320a-7b(b)(3)(B); 42 C.F.R. § 1001.952(i). This safe harbor was specifically not extended to independent contractors because of the "existence of widespread abusive practices by salespersons who are independent contractors and, therefore, who are not under appropriate supervision and control." Medicare and State Health Care Programs; Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35981 (July 29, 1991). Again, Defendants are not protected by this safe harbor because there is no employer-employee relationship.

70. TRUE HEALTH pays contractors, such as Defendant KEVIN CARRIER a commission based on a percentage of the laboratory's revenue in exchange for the contractor arranging for and recommending physicians who order tests that are reimbursed by federal programs. Defendants negotiated and entered into these agreements, knowing they violated anti-kickback statutes and, therefore, submitted false claims.

E. Defendants pay physicians' phlebotomists $15 per blood draw to induce physicians to order CVD panels

71. TRUE HEALTH, to induce physicians to order CVD panels, pays physicians' phlebotomists $15 for drawing blood from patients for tests submitted to TRUE HEALTH. In certain instances, TRUE HEALTH contracts directly with the phlebotomists, paying them as "independent contractors" for each blood draw they perform for tests submitted to TRUE HEALTH. Additionally, TRUE HEALTH encourages the physicians to reduce the phlebotomists' salaries by directing the

phlebotomists to "clock-out" when they draw blood for TRUE HEALTH tests submissions.

72. Furthermore, in an attempt to conceal this illegal kickback scheme TRUE HEALTH often utilizes a third-party company to enter into sham phlebotomy contracts with physicians to pay the physicians' phlebotomists the same $15 per blood draw. TRUE HEALTH sales representatives contact physicians with offers to make the physicians' phlebotomists "independent contractors" for the third-party company. Specifically, the phlebotomists are told that they can work as "independent contractors" of the third-party and receive compensation for every blood draw they perform for tests they submit to TRUE HEALTH. This is a sham designed to provide remuneration to physicians and their staff in exchange for CVD test panel orders to TRUE HEALTH.

73. TRUE HEALTH pays the third-party company a $25 draw and collection fee, per patient. From this payment, the third-party keeps approximately $10, and forwards the remaining $15 to its "independent contractors." This arrangement allows the physicians to reduce the salary they pay to the phlebotomists by having the phlebotomist "clock-out" when they draw blood for TRUE HEALTH. TRUE HEALTH encourages the physicians to have the phlebotomists "clock-out." TRUE HEALTH's arrangement with physicians and the third-party company is a deliberate violation of anti-kickback statutes.

74. Standard industry practice allows for the laboratory to pay physicians and medical assistants a nominal fee for the small amount of time it takes to draw, collect and package the specimen. Medicare, for example, provides a $3 payment to physicians for drawing a specimen.

75. According to the Department of Health and Human Services, Office of Inspector General (OIG), when a laboratory pays a referring physician for performing blood draws, and where the amount exceeds $3, "an inference arises that

the compensation is paid as an inducement to the physician to refer patients to the laboratory." OIG Advisory Opinion No. 05-08, page 4.

76. Here, TRUE HEALTH pays the third-party a $25 draw fee per patient, and the third-party forwards $15 of that fee to the phlebotomists. This remuneration is illegal as it induces physicians to order TRUE HEALTH CVD test panels. TRUE HEALTH's direct payments to physicians' phlebotomists are also illegal as they too induce physicians to order TRUE HEALTH CVD test panels.

VII. DEFENDANTS VIOLATED THE FEDERAL FALSE CLAIMS ACT BY BILLING FOR MEDICALLY UNNECESSARY LABORATORY TESTS

77. Defendants violated the False Claims Act by submitting claims for payment for laboratory testing services that Defendants knew were not medically necessary. Section 1862 of the Social Security Act provides, in pertinent part: "Notwithstanding any other provision of this title, no payment may be made under [Medicare] for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. 1395y(a)(1)(A).

78. Defendants violated 42 U.S.C. 1395y(a)(1)(A) by ordering medically unnecessary laboratory tests. Defendants' practice of pre-selecting tests and discouraging doctors from de-selecting a test violates established Medicare regulations as all diagnostic tests "must be ordered by the physician who furnishes a consultation or treats a beneficiary for a specific medical problem . . .", 42 C.F.R. § 410.32(a), and "tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." *Id.*

79. Medicare and other federal health care programs require as a condition of coverage that services rendered must be reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A). Defendants presented to Medicare claims for reimbursement of laboratory tests which were neither reasonable nor necessary. As such, each of these claims constitutes a false claim in violation of the False Claims

Act (31 U.S.C. § 3729 et seq.). Defendants certified, both explicitly and implicitly, that each claim they submitted to Medicare would fully comply with all statutes and regulations, and that as Medicare providers they would comply with all pertinent statutes and regulations.

A. Defendants require the ordering of extensive panels of duplicative and medically unnecessary tests

80. Defendants induced doctors to order panels comprised of tests that were not medically reasonable or necessary. Test requisition forms encourage physicians to order bundles, or "panels," of pre-selected tests, not all of which are necessary for each patient and were redundant tests. Specifically, physicians were encouraged to order only a "Baseline Panel" comprised of eighty-five different tests or a "Follow Up" Panel comprised of eighty-five tests. (See Exhibit 6). Defendants instructed physicians to simply circle the "B/L" or "F/U" box over the panel they wanted, regardless of the medical utility of the tests. By running each of these panels, Defendants were running duplicative and medically unnecessary tests.

81. As just one of many examples of unnecessary, duplicative tests, in TRUE HEALTH's "Baseline Panel," two of the eighty-five tests are the Apo-B and LDL-P tests. These same two tests are also part of the "Follow-Up" Panel. Both of these tests measure total LDL particles. There is no medical benefit to including both of these tests because they provide the same medical information and treatment would not be affected by including both tests. Both tests are pre-selected by Defendants as part of their panels; doctors do not have the option to de-select one of the tests. Defendants then perform, and bill Medicare for, each of the tests. Defendants charge Medicare in excess of $19.95 for the Apo-B test, and $42.93 for the LDL-P test. Each time they do so, Defendants violate the False Claims Act.

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VIII. DEFENDANTS VIOLATED MULTIPLE STATE FALSE CLAIMS ACTS BY CHARGING MEDICAID PROGRAMS IN EXCESS OF THEIR LOWEEST CHARGE AND PROVIDING PHYSICIANS WITH ILLEGAL KICK-BACKS

82. Title XIX of the Social Security Act and Title 42 of the Code of Federal Regulations authorize individual states to develop and manage their own Medicaid programs. Medicaid is a joint federal-state program that provides health care benefits, including laboratory services coverage, for certain groups including the poor and disabled. The funding for Medicaid is shared between the federal and state governments. Each state is required to implement a state plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. Id. The federal portion of each state's Medicaid payments, known as the Federal Medicaid Assistance Percentage is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d (b).

83. In addition to the Medicaid statutes, many states also have their own false claims statutes, which mirror the federal FCA. Defendants' schemes violated these state statutes. These violations are even more egregious because they have been accomplished through knowing violations of the long-established federal anti-kickback laws.

A. Defendants violated Georgia's lowest charge requirement

84. The Georgia Department of Community Health, Division of Medical Assistance ("Division") is solely responsible for the administration, including reimbursement to providers, of Georgia's Medicaid program. According to the Division's guidance, providers are required to bill the Division "their usual and customary fees," which was defined as "the lowest rate charged to private patients, other third party payers and insurance carriers, health maintenance organizations or other members of the general public for comparable services . . . includ[ing] any

special price or discounts offered to such patients." Schedule of Maximum Allowable Payments for Clinical Laboratory and Anatomical Pathology Services (given force of law by OCGA § 49-4-142).

85. The lowest rate limitation is also found in the Georgia Medicaid fee schedule "preamble" and in both the Georgia Medicaid Provider Manual ('Provider Manual'), and a similar manual specifically directed at laboratories (the Policies And Procedures For Independent Lab Services Program, or the 'Laboratory Provider Manual'). Indeed, the Georgia Medicaid fee schedule states:

> As required by Divisional policy, providers must bill the Division their usual and customary fees. "Usual and customary" means the lowest rate charged to private patients, other third party payers and insurance carriers, health maintenance organizations or other members of the general public for comparable services. The lowest rate includes any special price or discounts offered to such patients. Providers must not change their fees to the upper limits in this schedule, even if these fees are higher than the maximum allowable payments for the services rendered.

Schedule of Maximum Allowable Payments for Clinical Laboratory and Anatomical Pathology Services (emphasis added).

86. Both the Georgia Medicaid fee schedule and the Medicaid manual make expressly clear that the lowest charge rule is a condition of payment. Even more clearly, the Medicaid Provider Manual states, on its very first page: "This manual contains basic information concerning Georgia's Medicaid/PeachCare for Kids program and is intended for use by all participating providers. Along with the Statement of Participation, this manual encompasses the terms and conditions for receipt of reimbursement." *See* Exhibit 7 (Provider Manual), at 1 (emphasis added).

87. Simply put, TRUE HEALTH was required to bill Georgia Medicaid at its lowest price. Charges in excess of the maximum allowable fees are subject to recovery under both OCGA § 49-4-146.1, and the Georgia False Medicaid Claims Act, OGCA § 49-4-168 et seq.

88. Defendant TRUE HEALTH has contracted with private insurance provider United Healthcare, Aetna, and Cigna to provide them with lab tests at a

rate, on average 62% lower than the Georgia Medicaid reimbursement rate. (Exhibit 3). Under Georgia's Medicaid program, TRUE HEALTH is required to provide this same discount to Georgia's Medicaid program. Consequently, every test that TRUE HEALTH has billed Georgia's Medicaid program at a rate above their lowest rate to other payors constitutes a false claim.

89. Defendants' fraudulent schemes as detailed above have also defrauded Georgia's Medicaid program. Defendants submitted electronic invoices for clinical laboratory tests directly to the Division for Medicaid reimbursement, knowing both that the tests were induced by providing illegal kickbacks and the charges were in excess of the Medicaid reimbursement rate for each test performed. In submitting those claims for payment to the Division, Defendants represented that their fees complied with state Medicaid regulations. Those representations were false and violated the Georgia Medicaid statute, 49-4-146.1 and the Georgia False Medicaid Claims Act, OGCA § 49-4-168 et seq.

90. The chart included below provides examples of Defendants' overcharges to the Georgia Medicaid program and shows that Georgia Medicaid was billed and paid 62% more on average than other payors.

Test Name	CPT	GA Medicaid	United Health	Aetna	Cigna	Lowest Charge	% Over-charge
Lipid Panel	80061	$16.85	$8.42	$16.02	$12.56	$8.42	50%
Lp-PLAC2	83698	$42.69	$0.00	$0.00	$26.04	$0.00	100%
HS-CRP	86141	$16.28	$7.33	$15.49	$9.97	$7.33	55%
sd-LDL	83701	$31.21	$14.05	$0.00	$0.00	$0.00	100%
Lipoprotien (a)	83695	$16.28	$21.60	$41.10	$9.97	$9.97	39%
Apo A1	82172	$19.49	$0.00	$16.86	$11.82	$0.00	100%
Apo B	82172	$19.49	$0.00	$16.86	$11.82	$0.00	100%
Homocysteine	83090	$21.21	$10.61	$0.00	$12.93	$0.00	100%
Vitamin D	82306	$37.22	$18.61	$35.41	$22.71	$18.61	50%
Adiponectin	83516	$13.45	$7.25	$9.24	$8.86	$7.25	46%
C-Peptide	84681	$19.98	$13.08	$25.48	$16.06	$13.08	35%
Apo E	81401	$112.00	$69.55	$65.00	$0.00	$0.00	100%

Test Name	CPT	GA Medicaid	United Health	Aetna	Cigna	Lowest Charge	% Over-charge
Factor V Leiden	81241	$40.00	$54.68	$0.00	$0.00	$0.00	100%
Factor II	85201		$58.71	$50.58	$0.00		
MTHFR	81291	$40.00	$136.00	$0.00	$0.00	$0.00	100%
TSH	84443	$21.12	$10.56	$20.09	$12.93	$10.56	50%
Insulin	83525	$14.38	$7.19	$13.68	$8.86	$7.19	50%
Hemoglobin A1C	83036	$12.20	$6.10	$11.61	$7.39	$6.10	50%
Vitamin B-12	82607	$18.95	$9.48	$18.50	$11.63	$9.48	50%
Intact PTH	83970	$51.90	$25.45	$41.07	$31.76	$25.45	51%
T4, Free	84439	$11.34	$5.67	$8.97	$7.02	$5.67	50%
T4, Total	84436	$8.65	$4.32	$6.84	$5.35	$4.32	50%
T3, F	84481	$21.30	$10.65	$15.94	$13.11	$10.65	50%
T3, Total	84480	$16.03	$8.91	$14.11	$10.89	$8.91	44%
Testosterone, Total	84403	$32.47	$16.24	$25.69	$19.76	$16.24	50%
Testosterone, F	84402	$32.01	$16.01	$25.34	$19.57	$16.01	50%
Estradiol	82670	$35.14	$17.57	$27.81	$21.42	$17.57	50%
IGF-1	84305	$26.73	$13.37	$19.73	$16.25	$13.37	50%
Progesterone	84144	$25.61	$13.12	$20.75	$16.06	$13.12	49%
FSH	83001	$23.37	$11.69	$18.50	$14.22	$11.69	50%
LH	83002	$23.29	$11.65	$18.43	$14.22	$11.65	50%

B. Defendants violated Massachusetts's lowest charge requirement and Anti-Kick Back Rules

91. Massachusetts's Medicaid program, known as "MassHealth," is administered in part by the Commonwealth's Department of Health Care Finance and Policy ("DHCFP"). MassHealth's reimbursement procedures are governed, in part, by Massachusetts's Public Welfare statutes. Specifically, General Laws chapter 118E, section 41 prohibits providers from offering "any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind to induce" the purchase of services for which MassHealth pays.

92. The Code of Massachusetts Regulations also requires providers to bill MassHealth lowest of either the provider's "usual and customary charge," the

allowable fees listed in 114.3 CMR 20.05, or the rate recognized under 42 U.S.C. §§ 1395 1(h) for such tests. 1143. Code Mass. Regs. § 20.04(1). The Regulations define "usual and customary charge" as "[t]he lowest fee charged by an independent clinical laboratory for any laboratory service." 1143. Code Mass. Regs. § 20.05.

93. Charges in excess of the maximum allowable fees are subject to recovery under both the Medicaid provider statute, General Laws chapter 118E, § 38, and the Massachusetts False Claim Act, G.L. c. 12, §§ 5A-5O.

94. Defendant TRUE HEALTH has contracted with private insurance provider United Healthcare, Aetna, and Cigna to provide them with lab tests, on average at a rate 51% lower than the Medicare reimbursement rate (Exhibit 4). Under Massachusetts' Medicaid program, TRUE HEALTH is required to provide this same discount to Massachusetts' Medicaid program. Consequently, every test that TRUE HEALTH has billed Massachusetts' Medicaid program at a rate above their lowest rate to other payors constitutes a false claim.

95. Defendants' fraudulent schemes as detailed above have also defrauded the MassHealth program. Defendants submitted electronic invoices for clinical laboratory tests directly to DHCFP for MassHealth reimbursement, knowing both that the tests were induced by providing illegal kickbacks and the charges were in excess of the MassHealth reimbursement rate for each test performed. In submitting those claims for payment to MassHealth, Defendants represented that their fees complied with state MassHealth regulations. Those representations were false and violated the Medicaid provider statute, General Laws chapter 118E, § 38, and the Massachusetts False Claim Act, G.L. c. 12, §§ 5A-5O.

96. The chart included below provides examples of Defendants' overcharges to the Massachusetts Medicaid program and shows that Massachusetts Medicaid was billed and paid 51% more on average than other payors.

Test Name	CPT	MA Medicaid	United Health	Aetna	Cigna	Lowest Charge	% Over-charge
Lipid Panel	80061	$14.33	$8.42	$16.02	$12.56	$8.42	41%
Lp-PLAC2	83698	$36.32	$0.00	$0.00	$26.04	$0.00	100%
HS-CRP	86141	$13.85	$7.33	$15.49	$9.97	$7.33	47%
sd-LDL	83701	$26.56	$14.05	$0.00	$0.00	$0.00	100%
Lipoprotien (a)	83695	$13.85	$21.60	$41.10	$9.97	$9.97	28%
Apo A1	82172	$16.58	$0.00	$16.86	$11.82	$0.00	100%
Apo B	82172	$16.58	$0.00	$16.86	$11.82	$0.00	100%
Homocysteine	83090	$18.05	$10.61	$0.00	$12.93	$0.00	100%
Vitamin D	82306	$31.68	$18.61	$35.41	$22.71	$18.61	41%
Adiponectin	83516	$12.26	$7.25	$9.24	$8.86	$7.25	41%
C-Peptide	84681	$22.26	$13.08	$25.48	$16.06	$13.08	41%
Apo E	81401		$69.55	$65.00	$0.00	$0.00	
Factor V Leiden	81241		$54.68	$0.00	$0.00	$0.00	
MTHFR	81291		$136.00	$0.00	$0.00	$0.00	
TSH	84443	$17.98	$10.56	$20.09	$12.93	$10.56	41%
Insulin	83525	$12.23	$7.19	$13.68	$8.86	$7.19	41%
Hemoglobin A1C	83036	$10.39	$6.10	$11.61	$7.39	$6.10	41%
Vitamin B-12	82607	$16.01	$9.48	$18.50	$11.63	$9.48	41%
Intact PTH	83970	$44.16	$25.45	$41.07	$31.76	$25.45	42%
T4, Free	84439	$9.65	$5.67	$8.97	$7.02	$5.67	41%
T4, Total	84436	$7.35	$4.32	$6.84	$5.35	$4.32	41%
T3, F	84481	$18.13	$10.65	$15.94	$13.11	$10.65	41%
T3, Total	84480	$15.17	$8.91	$14.11	$10.89	$8.91	41%
Testosterone, Total	84403	$27.63	$16.24	$25.69	$19.76	$16.24	41%
Testosterone, F	84402	$27.25	$16.01	$25.34	$19.57	$16.01	41%
Estradiol	82670	$29.90	$17.57	$27.81	$21.42	$17.57	41%
IGF-1	84305	$18.09	$13.37	$19.73	$16.25	$13.37	26%
Progesterone	84144	$22.33	$13.12	$20.75	$16.06	$13.12	41%
FSH	83001	$19.88	$11.69	$18.50	$14.22	$11.69	41%
LH	83002	$19.82	$11.65	$18.43	$14.22	$11.65	41%

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C. Defendants Violated The California Insurance Fraud Prevention Act By Waiving Patient Co-Pays And Deductibles, And Providing Kickbacks

97. Pursuant to California Insurance Code § 1871.7(a), it is "unlawful to knowingly employ runners, cappers, steerers, or other persons to procure clients or patients to perform or obtain services or benefits pursuant . . . or to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis of a claim against an insured individual or his or her insurer."

98. Like the Federal False Claims Act, any person or entity that violates § 1871.7(a) is subject to a civil penalty of up to $10,000 for each claim submitted to an insurer for payment. The person or entity is also subject to treble damages for the amount of the claim for compensation billed to the insurer.

99. Defendants' fraudulent schemes circumvent insurance companies' safeguards against unreasonable and excessive charges for routine healthcare services. Under the Medicare program, "Routine waiver of deductibles and co-payments by charge-based providers, practitioners or suppliers is unlawful because it results in . . . false claims . . . [and] excessive utilization of items and services paid for by Medicare. HHS OIG Special Fraud Alerts, available at https://oig.hhs.gov/fruad/docs/alertsandbulletins/121994.html (Dec. 19, 1994).

100. Defendants' fraudulent kickback schemes outlined above also violate California Insurance Code § 1871.7(a), and therefore subject Defendants to treble damages for the amount of the claim for compensation billed to the insurer.

101. Managed care companies, such as Blues Cross/Blue Shield of California, United Healthcare, Aetna, and Cigna administer a variety of health and welfare benefit plans. As part of their fiduciary responsibilities to those plans, the managed care companies are responsible for controlling healthcare costs.

102. One way managed care companies control costs is by entering into networks of healthcare providers whereby the providers agree to accept fixed rates for services in exchange for access to plan members. The managed care companies'

arrangements with providers benefit the plans and their members by controlling overall health care costs and increasing the quality of medical care. Members who receive services from participating, or "in-network," providers benefit from the providers agreeing not to bill the patient for any difference between their plan's reimbursement to the provider and the provider's billed charge.

103. Plan members are free to use out-of-network providers, but the members must pay a portion of the cost (through co-payments, co-insurances or deductible payments) of treatment by out-of-network providers. Generally, out-of-network providers charge much higher rates than in-network providers, which incentivizes members to choose in-network providers and moderate their demand for out-of-network services. Likewise, the patient's burden in paying a portion of the costs ensures that providers are not charging rates untethered to the actual costs or market for providing medical services.

104. Defendants undermine this safeguard by fraudulently waiving patient deductibles and co-payments. Defendants lure patients from health plans administered by managed care companies by misrepresenting those patients' responsibilities under the plans, promising not to collect co-payments, and promising not to seek reimbursement for any remaining portion of the patients' bills that are uncovered by the plan.

105. By misleading plan members that they are not responsible for any deductible or co-payments, TRUE HEALTH increases the volume of its business while simultaneously increasing the damage to the managed care companies and the plans they serve.

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IX. CAUSES OF ACTION

FIRST CAUSE OF ACTION
On Behalf of the United States
Federal False Claims Act, Presenting False Claims
31 U.S.C. § 3729(a)(1)(A)

106. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 112 of this Complaint as though fully set forth herein.

107. Defendants knowingly (as defined in 31 U.S.C. § 3729(b)(1)) presented or caused to be presented false claims for payment or approval to an officer or employee of the United States.

108. Defendants knowingly presented false records and statements, including but not limited to bills, invoices, requests for reimbursement, and records of services, in order to obtain payment or approval of charges by the Medicare, Medicaid, and other government-funded programs that were higher than they were permitted to claim or charge by applicable law. Among other things, Defendants knowingly submitted false claims for Medicare, Medicaid, and other government programs' business that was obtained by means of, and as a result of, illegal kickbacks, and as a result of Defendants' illegally billing Medicare, Medicaid, and other government programs for (1) lab test that Defendants did not perform, in volumes in excess of thirty-percent of Defendants' total test volume; and (2) medically unnecessary test panels including medically unnecessary tests that Defendants pre-select.

109. Defendants knowingly made, used, and caused to be made and used false certifications that their claims, and all documents and data upon which those claims were based, were accurate, and were supplied in full compliance with all applicable statutes and regulations.

110. The conduct of Defendants violated 31 U.S.C. § 3729(a)(1)(A) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

SECOND CAUSE OF ACTION
On Behalf of the United States
Federal False Claims Act, Making or Using False Records or Statements Material to Payment or Approval of False Claims
31 U.S.C. § 3729(a)(1)(B)

111. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 110 of this Complaint as though fully set forth herein.

112. Defendants knowingly (as defined in 31 U.S.C. § 3729(b)(1)) made, used, or caused to be made or used false records or statements material to false or fraudulent claims.

113. Defendants knowingly made, used, and/or caused to be made and used false records and statements, including but not limited to bills, invoices, requests for reimbursement, and records of services, that were material to the payment or approval of charges by the Medicare, Medicaid, and other government programs that were higher than they were permitted to claim or charge by applicable law. Among other things, Defendants knowingly submitted false claims for Medicare, Medicaid, and other government programs' business that was obtained by means of, and as a result of, illegal kickbacks, and as a result of Defendants' illegally billing Medicare, Medicaid, and other government programs for (1) lab test that Defendants did not perform, in volumes in excess of thirty-percent of Defendants' total test volume; and (2) medically unnecessary panels including medically unnecessary tests that Defendants pre-select.

114. Defendant knowingly made, used, and caused to be made and used false certifications that its claims, and all documents and data upon which those claims were based, were accurate, and were supplied in full compliance with all applicable statutes and regulations.

115. The conduct of Defendants violated 31 U.S.C. § 3729(a)(1)(B) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

THIRD CAUSE OF ACTION
On Behalf of the United States
Federal False Claims Act, Conspiracy to Commit Violations
31 U.S.C. § 3729(a)(1)(C)

116. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 115 of this Complaint as though fully set forth herein.

117. Defendants knowingly (as defined in 31 U.S.C. § 3729(b)(1)) conspired to commit violations of substantive portions of the False Claims Act, including but not limited to subparagraphs (A), (B), and (G) of 31 U.S.C. § 3729.

118. Defendants conspired to: (1) knowingly present false records and statements; (2) knowingly make, use, and/or cause to be made and used false records and statements; and (3) knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

119. The conduct of Defendants violated 31 U.S.C. § 3729(a)(1)(C) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

FOURTH CAUSE OF ACTION
In the Alternative
On Behalf of the United States
Federal False Claims Act, Retention of Proceeds to Which Not Entitled
31 U.S.C. § 3729(a)(1)(G)

120. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 119 of this Complaint as though fully set forth herein.

121. In the alternative, Defendants knowingly made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

122. As discussed above, Defendants received far more money from the Medicare programs than it was entitled to. Defendants knew that they had received more money than it was entitled to, and avoided their obligation to return the excess money to the Government.

123. The conduct of Defendant violated 31 U.S.C. § 3729(a)(1)(G) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

FIFTH CAUSE OF ACTION
On Behalf of the State of California
California Insurance Frauds Prevention Act, Employment of Runners, Cappers and Steerers or Other Persons to Procure Patients
Cal. Ins. Code § 1871.7(a)
Against All Defendants

124. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 123 of this Complaint as though fully set forth herein.

125. Pursuant to California Insurance Code §1871.7(a), it is unlawful to knowingly employ runners, cappers, steerers, or other persons to procure patients for the purpose of submitting a claim to that patient's insurance carrier.

126. Defendants unlawfully incentivized physicians by waiving copays and deductibles and paying illegal remuneration in the form of kickbacks for the purpose of procuring more physicians to order tests, which were ultimately submitted to Medicare, Medicaid, other government programs, and private insurance companies for reimbursements. Defendants also pay contractors a commission based on a percentage of the laboratory's revenue in exchange for the contractor arranging for

and recommending physicians who order tests that are reimbursed by Medicare, Medicaid, and other government programs in violation of Cal. Ins. Code §1871.7(a). Defendants conspired together, and did so in order to submit claims for payment to insurance carriers in violation of Cal. Ins. Code §1871.7(a).

127. Because the claims submitted to medical insurers by Defendants were procured by runners, cappers, and steerers and other persons, these claims were false and fraudulent under the California Insurance Frauds Prevention Act.

128. This conduct was a substantial factor causing damages detailed herein.

SIXTH CAUSE OF ACTION
On Behalf of the State of California
California Insurance Frauds Prevention Act, Presenting or Causing to be Presented False or Fraudulent Claims for the Payment of An Injury Under A Contract of Insurance
Cal. Ins. Code § 1871.7(b); Cal. Pen. Code § 550(a)(1)
Against All Defendants

129. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 128 of this Complaint as though fully set forth herein.

130. Defendants have all either knowingly presented or caused to be presented false and fraudulent claims for reimbursement of tests, or conspired to present or cause to be presented such false and fraudulent claims.

131. These claims were fraudulent because:

- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for medically unreasonable and unnecessary tests.
- Defendants knowingly billed Medicare, Medicaid, other government programs, and private insurers for medically unnecessary and unreasonable tests.
- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for tests that were procured by means of, or otherwise involved, the payment of illegal kickbacks.

132. Defendants either directly presented such false claims for payment to insurers, or caused such false claims to be presented.

133. This conduct was a substantial factor causing damages detailed herein.

SEVENTH CAUSE OF ACTION
On Behalf of the State of California
California Insurance Frauds Prevention Act, Knowingly Preparing or Making Any Writing in Support of a False or Fraudulent Claim
Cal. Ins. Code § 1871.7(b); Cal. Pen. Code § 550(a)(5)
Against All Defendants

134. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 133 of this Complaint as though fully set forth herein.

135. Defendants have all either knowingly prepared, made, or subscribed a writing with an intent to present or use it, or to allow it to be presented, in support of false and fraudulent claims for the reimbursement of tests performed on patients, or have aided, abetted, and solicited, or conspired to make, or subscribe such a writing.

136. These writings include bills for payment presented to insurance carriers for payment, and invoices prepared in support of such bills for payment. Such bills for payment constitute false or fraudulent claims because through those bills:

- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for medically unreasonable and unnecessary tests.
- Defendants knowingly billed Medicare, Medicaid, other government programs, and private insurers for medically unnecessary and unreasonable tests.
- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for tests that were procured by means of, or otherwise involved, the payment of illegal kickbacks.

137. Defendants either directly presented such false claims for payment to insurers, or caused such false claims to be presented.

138. This conduct was a substantial factor causing damages detailed herein.

EIGHTH CAUSE OF ACTION
On Behalf of the State of California
California Insurance Frauds Prevention Act, Knowingly Making or Causing to be Made Any False or Fraudulent Claim for Payment of a Health Benefit
Cal. Ins. Code § 1871.7(b); Cal. Pen. Code § 550(a)(6)
Against All Defendants

139. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 138 of this Complaint as though fully set forth herein.

140. Defendants have all either knowingly presented or caused to be presented false and fraudulent claims for reimbursement of tests performed on patients, or have aided, abetted, and solicited, or conspired to present or cause to be presented such false and fraudulent claims.

141. The claims were false or fraudulent because:

- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for medically unreasonable and unnecessary tests.
- Defendants knowingly billed Medicare, Medicaid, other government programs, and private insurers for medically unnecessary and unreasonable tests
- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for tests that were procured by means of, or otherwise involved, the payment of illegal kickbacks.

142. Defendants either directly presented such false claims for payment to insurers, or caused such false claims to be presented.

143. This conduct was a substantial factor causing damages detailed herein.

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NINTH CAUSE OF ACTION
On Behalf of the State of California
California Insurance Frauds Prevention Act, Soliciting, Accepting, and Referring Business To or From an Individual or Entity That Intends to Violate Section 550 of the Penal Code or Section 1871.4 of the Insurance Code
Cal. Ins. Code § 1871.7(b); Cal. Pen. Code § 549
Against All Defendants

144. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 143 of this Complaint as though fully set forth herein.

145. Defendants have solicited, accepted, or referred business to or from an entity or individual that intended to violate Section 550 of the Penal Code or Section 1871.4 of the Insurance Code.

146. The claims were false or fraudulent because:

- Defendants knowingly billed Medicare, Medicaid, other government programs, and private insurers for medically unnecessary and unreasonable tests.
- Defendants knowingly billed Medicare and private insurers for medically unnecessary and unreasonable tests.
- Defendants knowingly sought and falsely represented that they were entitled to reimbursement for tests that were procured by means of, or otherwise involved, the payment of illegal kickbacks.

147. Defendants either directly presented such false claims for payment to insurers, or caused such false claims to be presented.

148. This conduct was a substantial factor causing damages detailed herein.

TENTH CAUSE OF ACTION
On Behalf of the Commonwealth of Massachusetts Massachusetts False Claims Act, Presenting False Claims Massachusetts General Laws chapter 12, § 5B(1)
Against All Defendants

149. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 148 of this Complaint as though fully set forth herein.

150. At all times relevant hereto, Defendants, and each of them, knowingly (as defined in Massachusetts General Laws chapter 12, section 5A) presented, or caused to be presented, claims for payment or approval in the form of invoices submitted to MassHealth that reflected prices higher than the maximum reimbursement rates allowed by law. Specifically, Defendants, and each of them, submitted or caused to be submitted invoices for payment of MassHealth covered clinical laboratory tests at amounts grossly in excess of the amounts contemplated by law, resulting in great financial loss to the Commonwealth.

151. Defendants' conduct violated Massachusetts General Laws chapter 12, section 5B(1), and was a substantial factor in causing the Commonwealth to sustain damages in an amount according to proof pursuant to Massachusetts General Laws chapter 12, section 5B.

ELEVENTH CAUSE OF ACTION
Massachusetts False Claims Act, Making or Using False Records or Statements To Obtain Payment or Approval of False Claims Massachusetts General Laws chapter 12, § 5B(2)
Against All Defendants

152. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 151 of this Complaint as though fully set forth herein.

153. At all times relevant hereto, Defendants, and each of them, knowingly (as defined in Massachusetts General Laws chapter 12, section 5A) made or used, or caused to be made or used, false records or statements to obtain payment or approval of false claims. Specifically, Defendants billed the DHCFP at rates equal to or in excess of the maximum rates specified by the MassHealth rate schedule, rather than the discounted rates offered to others.

154. Defendants' conduct violated Massachusetts General Laws chapter 12, section 5B(2), and was a substantial factor in causing the Commonwealth to sustain damages in an amount according to proof pursuant to Massachusetts General Laws chapter 12, section 5B.

TWELFTH CAUSE OF ACTION
On Behalf of the Commonwealth of Massachusetts
Massachusetts False Claims Act, Retention of Proceeds Of Inadvertently Submitted False Claims Massachusetts General Laws chapter 12, § 5B(9)
Against All Defendants

155. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 154 of this Complaint as though fully set forth herein.

156. Plaintiff is informed and believes, and on that basis alleges, that as to each claim for MassHealth reimbursement submitted for a test as to which the Defendant charged other clients less than it charged to DHCFP, each Defendant: (a) was a beneficiary of an inadvertent submission of a false claim to DHCFP; (b) subsequently discovered the falsity of the claim; (c) and failed to disclose the false claim to DHCFP within a reasonable time after discovery of the false claim. Specifically, each Defendant billed DHCFP at rates equal to or in excess of the maximum rates specified by the MassHealth rate schedule, rather than the discounted rates offered to others, and on discovering that it had done so, failed to promptly disclose the overcharge to DHCFP and make restitution therefor.

157. Defendants' conduct violated Massachusetts General Laws chapter 12, section 5B(9) and was a substantial factor in causing the Commonwealth to sustain damages in an amount according to proof pursuant to Massachusetts General Laws chapter 12, section 5B.

THIRTEENTH CAUSE OF ACTION
On Behalf of the State of Georgia
Georgia False Medicaid Claims Act, Presenting False Claims OCGA § 49-4-168.1(a)(1)
Against All Defendants

158. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 157 of this Complaint as though fully set forth herein.

159. At all times relevant hereto, Defendants, and each of them knowingly (as defined in OCGA § 49-4-168(2)) presented, or caused to be presented, claims for

payment or approval in the form of invoices submitted to Medicaid that reflected prices higher than the maximum reimbursement rates allowed by law. Specifically, Defendants, and each of them, submitted or caused to be submitted invoices for payment in excess of the amounts contemplated by law, resulting in great financial loss to the State.

FOURTEENTH CAUSE OF ACTION
On Behalf of the State of Georgia
Georgia False Medicaid Claims Act, Making or Using False Records or Statements
Against All Defendants

160. Plaintiffs incorporate by reference and reallege all of the allegations contained in paragraphs 1 through 159 of this Complaint as though fully set forth herein.

161. At all times relevant hereto, Defendants, and each of them, knowingly (as defined in OCGA § 49-4-168(2)) made or used, or caused to be made or used, false records or statements to obtain payment or approval of false claims. Specifically, Defendant billed the Division at rates equal to or in excess of the maximum rates specified by the Medicaid rate schedule, rather than the discounted rates offered to others.

162. Defendants' conduct violated OCGA § 49-4-168.1(a)(2), and was a substantial factor in causing the State to sustain damages in an amount according to proof pursuant to OCGA § 49-4-168.1(a).

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs by and through Relator, pray judgment in its favor and against Defendants as follows:

163. Defendants' conduct violated the Federal False Claims Act, the California Insurance Frauds Prevention Act, the Georgia False Claims Act, and the Massachusetts False Claims Act, and was a substantial factor in causing the United States and the states of California, Georgia, and Massachusetts to sustain damages in an amount according to proof pursuant to the Federal False Claims Act, the

California Insurance Frauds Prevention Act, the Georgia False Claims Act, and the Massachusetts False Claims Act . That judgment be entered in favor of plaintiffs UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF GEORGIA, and THE COMMONWEALTH OF MASSACHUSETTS ex rel. STF, LLC, and against Defendants TRUE HEALTH DIAGNOSTICS, LLC, JEFFREY P. "BOOMER" CORNWELL, CHRIS GROTTENTHALER, CAROL NELLIS, SAM FILLNGANE, KEVIN CARRIER, CHARLES MAIMONE, according to proof, as follows:

a. On the **First Cause of Action** (Presenting False Claims (31 U.S.C. § 3729(a)(1)(A))) damages as provided by 31 U.S.C. § 3729(a)(1), in the amount of:

   i. Triple the amount of damages sustained by the Government;

   ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

   iii. Recovery of costs;

   iv. Pre- and post-judgment interest;

   v. Such other and further relief as the Court deems just and proper;

b. On the **Second Cause of Action** (False Claims Act; Making or Using False Records or Statements Material to Payment or Approval of False Claims (31 U.S.C. § 3729(a)(1)(B))) damages as provided by 31 U.S.C. § 3729(a)(1) in the amount of:

   i. Triple the amount of damages sustained by the Government;

   ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

   iii. Recovery of costs;

   iv. Pre- and post-judgment interest;

   v. Such other and further relief as the Court deems just and proper;

c. On the **Third Cause of Action** (False Claims Act; Conspiracy to Commit Violations (31 U.S.C. § 3729(a)(1)(C))) damages as provided by 31 U.S.C. § 3729(a)(1) in the amount of:

i. Triple the amount of damages sustained by the Government;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs;

iv. Pre- and post-judgment interest;

v. Such other and further relief as the Court deems just and proper;

d. On the **Fourth Cause of Action** (False Claims Act, Retention of Proceeds to Which Not Entitled (31 U.S.C. § 3729(a)(1)(G))) damages as provided by 31 U.S.C. § 3729(a)(1) in the amount of:

i. Triple the amount of damages sustained by the Government;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs;

iv. Pre- and post-judgment interest;

v. Such other and further relief as the Court deems just and proper.

e. On the **Fifth, Sixth, Seventh, Eighth, and Ninth Causes of Action** (California Insurance Frauds Prevention Act §§ 1871.7(a) and (b) and California Penal Code §§550(a)(1); 550(a)(5); 550(a)(6) and 549) damages as provided by California Insurance Frauds Prevention Act §§ 1871.7, et seq., in the amount of:

i. Civil penalties of Eleven Thousand Dollars ($11,000) for each false and fraudulent claim submitted, presented or caused to be submitted or presented to an insurance company;

ii. Assessments of three-times the amount of each claim for compensation made by Defendants;

iii. Recovery of costs;

iv. Pre- and post-judgment interest;

v. Such other and further relief as the Court deems just and proper

f. On the **Tenth Cause of Action** (Massachusetts False Claims Act; Presentation of False Claims to Massachusetts (Massachusetts General Laws chapter 12, section 5B(1))), damages as provided by Massachusetts General Laws chapter 12, section 5B in the amount of:

i. Triple the amount of the Commonwealth's damages;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs, attorneys' fees and expenses;

iv. Such other and further relief as the Court deems just and proper;

g. On the **Eleventh Cause of Action** (Massachusetts False Claims Act; Causing False Records or Statements To Be Made or Used To Get False Claims Paid or Approved By Massachusetts (Massachusetts General Laws chapter 12, section 5B(2))), damages as provided by Massachusetts General Laws chapter 12, section 5B in the amount of:

i. Triple the amount of the Commonwealth's damages;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs, attorneys' fees and expenses;

iv. Such other and further relief as the Court deems just and proper.

h. On the **Twelfth Cause of Action** (Massachusetts False Claims Act; Retention of Proceeds Of Inadvertently Submitted False Claims (Massachusetts General Laws chapter 12, section 5B(9))) damages as provided by Massachusetts General Laws chapter 12, section 5B in the amount of:

i. Triple the amount of the State's damages;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs, attorneys' fees and expenses;

iv. Such other and further relief as the Court deems just and proper.

i. On the **Thirteenth Cause of Action** (Georgia False Medicaid Claims Act; Presentation of False Claims to Georgia (OCGA § 49-4-168.1(a)(1)), damages as provided by OCGA § 49-4-168.1(a) in the amount of:

i. Triple the amount of the State's damages;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs, attorneys' fees and expenses pursuant to OCGA § 49-4-168.2(i);

iv. Such other and further relief as the Court deems just and proper;

j. On the **Fourteenth Cause of Action** (Georgia False Medicaid Claims Act; Causing False Records or Statements To Be Made or Used To Get False Claims Paid or Approved By Georgia (OCGA § 49-4-168.1(a)(2)), damages as provided by OCGA § 49-4-168.1(a) in the amount of:

i. Triple the amount of the State's damages;

ii. Civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

iii. Recovery of costs, attorneys' fees and expenses pursuant to OCGA § 49-4-168.2(i);

iv. Such other and further relief as the Court deems just and proper.

164. Further, Relator, on its own behalf, pursuant to 31 U.S.C. section 3730(d), California Insurance Frauds Prevention Act §§ 1871.7(g)(1)(A), and the False Claims Acts and applicable laws of California, Georgia, and Massachusetts

requests that Relator receive such maximum amount as permitted by law, of the proceeds of this action or settlement of this action collected by the United States, California, Georgia, and/or Massachusetts plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action. Relator requests that its percentage be based upon the total value recovered, including any amounts received from individuals or entities not parties to this action.

Respectfully Submitted,

Dated: October 21, 2015 **COTCHETT, PITRE & McCARTHY, LLP**

By: _____
NIALL P. McCARTHY
JUSTIN T. BERGER
ERIC J. BUESCHER

Attorneys for Relator STF, LLC

XI. DEMAND FOR JURY TRIAL

Relator STF, LLC hereby demands a jury trial on all issues so triable.

Respectfully Submitted,

Dated: October 21, 2015 **COTCHETT, PITRE & McCARTHY, LLP**

By: _____
NIALL P. McCARTHY
JUSTIN T. BERGER
ERIC J. BUESCHER

Attorneys for Relator STF, LLC

Exhibit 1

Dear ,

Today I had a fairly long phone call with Michael, my new True Health rep. He was the rep for several years for HDL and identified himself as my new HDL rep at first!!

He assured me that all would be exactly as it had been when HDL was the dominant player and I'd see no differences from before. Only the name would be different. The reports would be identical and the billing policies would be identical.

I reminded him that I'd never used HDL so he needed to explain all to me and he did.

PANELS and LABS:

He said they'd put their standard panels together for me, consisting of ALL of their tests (panel 1)!!

If the patient was 100% normal and no goals were created then ALL the labs would be repeated in a year, except for the genetic tests (panel 2) If ANY labs were abnormal, they recommended repeating ALL labs (with panel 2... as I said... this is same as panel 1....all of their labs...minus the genetic markers) and the panel should be run every 3 months.

He said this is what about all his clients do... Quote... 95%!!!

He said they have a proprietary NMR... using a new type of machine to run it only they had

He said they had a proprietary Omega 3 which used RBCs... and was much better than others!!

He said they have a proprietary sterol test.

BILLING POLICY:

He said that if a patient had ANY US health insurance, except for a Federal Plan, such as TriCare or Blue Shield Federal.. In which case they need to bill for deductibles and copays, the cost to all patients is always ZERO!! No patients would ever see a bill or ever have a penny to pay!! This includes Medicare, Medical (Medicaid), PPOs, EPOs, all HMOs!!!

PAYMENT FOR PHLEBOTOMIST:

He said they take your own staff who draw blood and make them part time contracted employees with a company called BioTech... a phlebotomy company(???) The staff then theoretically "clock out" on and off all day long between the two employment situations. He said I could just reduce their salaries for the extra money earned through the contracted arrangement. The pay is $15 a draw. He said a 1099 would be issued.

ADDITIONAL BENEFITS:

They would provide a free health coach who would work one on one with my patients. They provide meal plans, dietary advice, and stress management, along with a mobile app. All conversations are emailed back to the doctor.

It is absolutely back to business as usual! As much as I thought this would happen, a part of me really couldn't believe they would have the gall to just resume all the same behaviors!!

He scheduled to come to my office on October 13th to get us started!!

Exhibit 2

TRUE HEALTH DIAGNOSTICS

HealthDiagnosticLaboratoryInc.

Beyond disease diagnosis

September 30, 2015

Dear Provider,

True Health Diagnostics is pleased to announce the successful purchase of Health Diagnostic Laboratory, Inc. (HDL, Inc.) assets through the bankruptcy process. Together, this represents an incredible opportunity to combine the patient-centric, clinical and scientific philosophy shared by both organizations to continue the mission to accurately diagnose, manage and prevent cardiovascular and metabolic disease. Together, True Health Diagnostics and HDL, Inc. stand firm in our shared commitments to you:

- **Exceptional Customer Service and Innovative Scientific Research** – For you, our valued customer, fighting on the front line of these disorders, this is a further demonstration of our commitment to an even greater level of service and support, a deeper commitment of partnership and the continued development of more first-class tools to help you achieve the improvement in outcomes you have already experienced within your patient populations through advanced diagnostics.
- **Compliance and transparency** – True Health Diagnostics embraces the same principles and requirements set forth in the Corporate Integrity Agreement with the Office of the Inspector General to which HDL, Inc. is a party, and will incorporate it into THD. True Health Diagnostics and HDL, Inc. have shared values with regard to the importance of compliance with federal and state healthcare regulatory requirements in connection with oversight and management of its business operations.
- **What do I need to do in order to continue to have HDL, Inc. or True Health Diagnostics run my lab tests?** – Nothing, we intend to make these changes seamless and "business as usual." Please note that any order placed to HDL, Inc. will be received and processed by True Health Diagnostics, LLC.
- **Expectations for next 30 to 60 days** – In general, your sales representative will remain the same. If there are any changes, we will notify you in the next week. In the meantime, you can contact Sales Support at ext. 1900. We look forward to continuing to provide exceptional service and are committed to developing even more useful tools. Please note the following:
  - Use patient kit materials from either True Health or HDL, Inc.
  - Use requisitions from either True Health or HDL, Inc.
  - Continue to access the same Provider Portal for order entry or to access patient reports.
  - Test menu options will soon include all assays currently offered by HDL, Inc. and THD.
  - Beginning early October, all providers will receive results in the HDL, Inc. format which offers robust clinical education content.
  - Temporarily, you may receive materials with either the HDL, Inc. or THD branding; these materials are interchangeable.

We look forward to providing further updates in the future and will continue to provide excellent customer service. Our dedicated sales representatives and client service teams (1-877-443-5227) are ready to answer any questions you may have.

Sincerely,

Chris Greltenthaler
Chief Executive Officer – True Health Diagnostics, LLC
www.truehealthdx.com 1-877-443-5227

Exhibit 3

Medicaid Lowest Charge

10/13/2015

Payors	CPT	GA Medicaid	United Health	Aetna	Cigna	Lowest Charge	% Overcharge
Lipid Panel	80061	$16.85	$8.42	$16.02	$12.56	$8.42	50%
Lp-PLAC2	83698	$42.69	$0.00	$0.00	$26.04	$0.00	100%
HS-CRP	86141	$16.28	$7.33	$15.49	$9.97	$7.33	55%
sd-LDL	83701	$31.21	$14.05	$0.00	$0.00	$0.00	100%
Lipoprotien (a)	83695	$16.28	$21.60	$41.10	$9.97	$9.97	39%
Apo A1	82172	$19.49	$0.00	$16.86	$11.82	$0.00	100%
Apo B	82172	$19.49	$0.00	$16.86	$11.82	$0.00	100%
Homocysteine	83090	$21.21	$10.61	$0.00	$12.93	$0.00	100%
Vitamin D	82306	$37.22	$18.61	$35.41	$22.71	$18.61	50%
Adiponectin	83516	$13.45	$7.25	$9.24	$8.86	$7.25	46%
C-Peptide	84681	$19.98	$13.08	$25.48	$16.06	$13.08	35%
Apo E	81401	$112.00	$69.55	$65.00	$0.00	$0.00	100%
Factor V Leiden	81241	$40.00	$54.68	$0.00	$0.00	$0.00	100%
Factor II	85201		$58.71	$50.58	$0.00		
MTHFR	81291	$40.00	$136.00	$0.00	$0.00	$0.00	100%
TSH	84443	$21.12	$10.56	$20.09	$12.93	$10.56	50%
Insulin	83525	$14.38	$7.19	$13.68	$8.86	$7.19	50%
Hemoglobin A1C	83036	$12.20	$6.10	$11.61	$7.39	$6.10	50%
Vitamin B-12	82607	$18.95	$9.48	$18.50	$11.63	$9.48	50%
Intact PTH	83970	$51.90	$25.45	$41.07	$31.76	$25.45	51%
T4, Free	84439	$11.34	$5.67	$8.97	$7.02	$5.67	50%
T4, Total	84436	$8.65	$4.32	$6.84	$5.35	$4.32	50%
T3, F	84481	$21.30	$10.65	$15.94	$13.11	$10.65	50%
T3, Total	84480	$16.03	$8.91	$14.11	$10.89	$8.91	44%
Testerone, Total	84403	$32.47	$16.24	$25.69	$19.76	$16.24	50%
Testosterone, F	84402	$32.01	$16.01	$25.34	$19.57	$16.01	50%
Estradiol	82670	$35.14	$17.57	$27.81	$21.42	$17.57	50%
IGF-1	84305	$26.73	$13.37	$19.73	$16.25	$13.37	50%
Progesterone	84144	$25.61	$13.12	$20.75	$16.06	$13.12	49%
FSH	83001	$23.37	$11.69	$18.50	$14.22	$11.69	50%
LH	83002	$23.29	$11.65	$18.43	$14.22	$11.65	50%

Average Overpayment **62%**

GA

Exhibit 4

Medicaid Lowest Charge

10/13/2015

Payors	CPT	MA Medicaid	United Health	Aetna	Cigna	Lowest Charge	% Overcharge
Lipid Panel	80061	$14.33	$8.42	$16.02	$12.56	$8.42	41%
Lp-PLAC2	83698	$36.32	$0.00	$0.00	$26.04	$0.00	100%
HS-CRP	86141	$13.85	$7.33	$15.49	$9.97	$7.33	47%
sd-LDL	83701	$26.56	$14.05	$0.00	$0.00	$0.00	100%
Lipoprotien (a)	83695	$13.85	$21.60	$41.10	$9.97	$9.97	28%
Apo A1	82172	$16.58	$0.00	$16.86	$11.82	$0.00	100%
Apo B	82172	$16.58	$0.00	$16.86	$11.82	$0.00	100%
Homocysteine	83090	$18.05	$10.61	$0.00	$12.93	$0.00	100%
Vitamin D	82306	$31.68	$18.61	$35.41	$22.71	$18.61	41%
Adiponectin	83516	$12.26	$7.25	$9.24	$8.86	$7.25	41%
C-Peptide	84681	$22.26	$13.08	$25.48	$16.06	$13.08	41%
Apo E	81401		$69.55	$65.00	$0.00	$0.00	
Factor V Leiden	81241		$54.68	$0.00	$0.00	$0.00	
MTHFR	81291		$136.00	$0.00	$0.00	$0.00	
TSH	84443	$17.98	$10.56	$20.09	$12.93	$10.56	41%
Insulin	83525	$12.23	$7.19	$13.68	$8.86	$7.19	41%
Hemoglobin A1C	83036	$10.39	$6.10	$11.61	$7.39	$6.10	41%
Vitamin B-12	82607	$16.01	$9.48	$18.50	$11.63	$9.48	41%
Intact PTH	83970	$44.16	$25.45	$41.07	$31.76	$25.45	42%
T4, Free	84439	$9.65	$5.67	$8.97	$7.02	$5.67	41%
T4, Total	84436	$7.35	$4.32	$6.84	$5.35	$4.32	41%
T3, F	84481	$18.13	$10.65	$15.94	$13.11	$10.65	41%
T3, Total	84480	$15.17	$8.91	$14.11	$10.89	$8.91	41%
Testerone, Total	84403	$27.63	$16.24	$25.69	$19.76	$16.24	41%
Testosterone, F	84402	$27.25	$16.01	$25.34	$19.57	$16.01	41%
Estradiol	82670	$29.90	$17.57	$27.81	$21.42	$17.57	41%
IGF-1	84305	$18.09	$13.37	$19.73	$16.25	$13.37	26%
Progesterone	84144	$22.33	$13.12	$20.75	$16.06	$13.12	41%
FSH	83001	$19.88	$11.69	$18.50	$14.22	$11.69	41%
LH	83002	$19.82	$11.65	$18.43	$14.22	$11.65	41%

Average Overpayment **51%**

MA

Exhibit 5

---------- Forwarded message ----------
Date: Tue, Sep 22, 2015 at 9:25 PM
Subject: Fwd: True Health Diagnostics
To:

Dear ,
Here is the email correspondence I had with the rep from True Health, a former rep for HDL....
I had conversations with this rep and also with a female VP who also was at the Florida exhibit hall for the A4M conference in May 2015. I must search for her business card but it shouldn't be hard to determine who she was.
At the time, she told me that she was very excited about me and planned to attend my lecture!! We were very friendly together.
She excitedly disclosed that she was interested in my becoming a speaker for True Health.... That may actually still be an option.

In summary, what they told me about True Health was that the company would bill private insurance and might have to even bill the patients, but that I should not worry as they never actually required that patients pay anything. I therefore should not be concerned about the costs to patients...and should order whatever I felt I wanted to order. I could have panels of tests to facilitate my ordering.
Medicare was always entirely free to patients.
I was not offered any compensation, nor did I bring that subject up at all.

Regards,

From: Kevin Hotmail <kcarrier212@hotmail.com>
Date: May 10, 2015 at 1:44:56 PM PDT

Subject: True Health Diagnostics

Dr.

Hey there! It sure was a pleasure to meet you at the recent A4M meeting in Hollywood. I trust that your travels were safe, uneventful and you have made it back to the comfort of home.

As I promised, I wanted to forward on some initial information and take the opportunity to reintroduce your practice to True Health Diagnostics.

True Health Diagnostics is a start up laboratory focused on the comprehensive health of the patient. True Health Diagnostics will offer testing to uncover underlying disease in multiple chronic disease states. Our initial focus will be on cardiovascular and metabolic disease. True Health Diagnostics is a value based lab, meaning we intend to deliver ninety-five percent of the clinical value at half the cost. Our intention at True Health Diagnostics is to protect the provider and the patient by delivering high value testing while at the same time minimizing, if not eliminating unnecessary and investigational testing. We believe by doing this we can provide a high level of care to the patient without exposing the patient to unreasonable bills nor exposing the provider to extensive scrutiny by payors.

I have attached an example case study. Please keep in mind that this report is different than what you picked up in Hollywood. This is what the report will look like in approximately 2 to 3 weeks. With that being said, it is last draft and does contain some typos and reference ranges/results might not be accurate at this time.

I hope that your practice will give myself and True Health Diagnostics the chance to earn your business. We believe our focus on quality, customer service and value will afford the opportunity to become a leader in advanced diagnostics. In the future True Health

Diagnostics will expand the offering into multiple disease states with multiple unique platforms. True Health Diagnostics will deliver disease management via multiple media options designed with the patient in mind.

Once again, it was was a great pleasure to have met you this weekend.

Sincerely,

Kevin Carrier

True Health Diagnostics

Disease Management Consultant – Southeast Area

(251) 458-0293

Laboratory Test Results

TRUE HEALTH DIAGNOSTICS
EMPOWERING HEALTH THROUGH INSIGHT

6170 Research Road, Frisco, TX 75033
Phone or Fax: 866-953-2553

Account Information	
Account No	TXTHD0175033
Physician	Kent Mitchell Ph.D.
Practice	True Health
NPI	1619376316
Address	6170 Research Road Frisco, TX 75033

Patient Information	
Name	Man, Iron C.
Phone	(123) 456-7890
Sex	Male
DOB	01/01/1911
Specimen ID	A1412190008
BMI	30

Traditional Cholesterol

Test	02/02/2015	Historical Results 00/00/0000	00/00/0000	Baseline 00/00/0000	Optimal	Intermediate	High Risk	Unit
Total Cholesterol	250	134	184	164	<200	200 - 239	>=240	mg/dL
HDL-C	30	134	184	164	>60	41 - 60	<=40	mg/dL
Non-HDL Calculation	99	164	184	164	<100	100 - 129	>=130	mg/dL
LDL-C	184	164	134	184	<130	130 - 159	>=160	mg/dL
Triglycerides	180	134	184	164	<150	150 - 199	>=200	mg/dL

Advanced CVD Monitoring

Test	02/02/2015	Historical Results 00/00/0000	00/00/0000	Baseline 00/00/0000	Optimal	Intermediate	High Risk	Unit
Apo B	60	134	184	164	<60	60 - 79	>=80	mg/dL
LDL-P	1152	134	184	164	<1000	1000 - 1299	>1300	umol/L
sdLDL	50	164	184	164	<35	35 - 48.6	>=48.7	mg/dL
HDL-P	35	164	134	184	>=34	29 - 35	<28	umol/L
HDL Size	8.5	134	184	164	>9.6	8.8 - 9.6	<=8.9	nm
Apo A-1	141	164	134	184	>150	131 - 149	<130	mg/dL
Apo B / A-1 Ratio	.58	134	184	164	<=.60	.61 - .80	>=0.81	mg/dL
Lp(a) Mass	29	134	184	164	<30	30	>=31	mg/dL
OxyLDL	60	134	184	164	<60	60 - 79	>=80	mg/dL

Collection Date: 12/19/2014
Received Date: 12/19/2014
Report Date: 12/19/2014

Specimen ID: A1412190008
Lab Director: Kent R. Mitchell, Ph.D.
Report Type: Final

CLIA No. 45D2082195 | NPI No. 1619376316
Printed: 12/19/2014 16:13

Laboratory Test Results

TRUE HEALTH DIAGNOSTICS
EMPOWERING HEALTH THROUGH INSIGHT

6170 Research Road, Frisco, TX 75033
Phone or Fax: 866-953-2553

Account Information	
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Physician	Kent Mitchell Ph.D.
Practice	True Health
NPI	1619376316
Address	6170 Research Road Frisco, TX 75033

Patient Information	
Name	Man, Iron C.
Phone	(123) 456-7890
Sex	Male
DOB	01/01/1911
Specimen ID	A1412190008
BMI	30

Diabetic/ Prediabetic

Test	02/02/2015	Historical Results 00/00/0000	00/00/0000	Baseline 00/00/0000	Optimal	Intermediate	High Risk	Unit
Glucose	110	134	184	164	70 - 90	100 - 125	>125	mg/dL
Insulin	8.0	134	184	164	>= 10	5.6 - 9	<=5.5	ug/mL
C-Peptide	3.0	164	184	164	<= 9	10 - 19	>=20	µg/mL
Proinsulin	9.8	164	134	184	<5.5	5.5 - 6.4	>=6.5	%
GlycoMark	234	134	184	164	<100	100 - 139	>140	mg/dL
A1c	4.4	134	184	164	1.0 - 3.0	3.1 - 4.5	>=4.6	ng/mL
EAG	22	134	184	164	0.2 - 23	23	>=24	µg/dL
Fructosomine	22	164	184	164	>= 17	9 - 16	<=8	µg/mL
Cortisol	69	164	134	184	1 - 62		63 - 120	µg/mL
Adiponectin	42	134	184	164	1 - 60		60 - 200	mg/mL
Leptin	110	134	184	164	70 - 90	100 - 125	>125	mg/dL
Quantos IR	8.0	134	184	164	>= 10	5.6 - 9	<=5.5	ug/mL
Alpha hydroxybutyric	3.0	164	184	164	<= 9	10 - 19	>=20	µg/mL
Linoleoylglycero	9.8	164	134	184	<5.5	5.5 - 6.4	>=6.5	%
Oleic acid	234	134	184	164	<100	100 - 139	>140	mg/dL
Quantos IGT	4.4	134	184	164	1.0 - 3.0	3.1 - 4.5	>=4.6	ng/mL
Beta hydroxybutyric acid	22	134	184	164	0.2 - 23	23	>=24	µg/dL
Alpha hydroxybutyric	22	164	184	164	>= 17	9 - 16	<=8	µg/mL
Linoleoylglycero	69	164	134	184	1 - 62		63 - 120	µg/mL
Oleic acid	42	134	184	164	1 - 60		60 - 200	mg/mL
4 methyl 2	110	164	134	184	70 - 90	100 - 125	>125	mg/dL
Serine	8.0	134	184	164	>= 10	5.6 - 9	<=5.5	ug/mL
Anti-GAD	3.0	134	184	164	<= 9	10 - 19	>=20	µg/mL
Pro-Insulin/Insulin Ratio	9.8	134	184	164	<5.5	5.5 - 6.4	>=6.5	%
Leptin/BMI Ratio	234	164	184	164	<100	100 - 139	>140	mg/dL
Pro-Insulin/C-Peptide Ratio	4.4	164	134	184	1.0 - 3.0	3.1 - 4.5	>=4.6	ng/mL

Laboratory Test Results

TRUE HEALTH DIAGNOSTICS
EMPOWERING HEALTH THROUGH INSIGHT

6170 Research Road, Frisco, TX 75033
Phone or Fax: 866-953-2553

Account Information	
Account No	TXTHD0175033
Physician	Kent Mitchell Ph.D.
Practice	True Health
NPI	1619376316
Address	6170 Research Road Frisco, TX 75033

Patient Information	
Name	Man, Iron C.
Phone	(123) 456-7890
Sex	Male
DOB	01/01/1911
Specimen ID	A1412190008
BMI	30

Metabolic

Test	02/02/2015	Historical Results 00/00/0000	00/00/0000	Baseline 00/00/0000	Optimal	Intermediate	High Risk	Unit
25-OH Vitamin D	22	134	184	164	> 31	15 - 31	< = 14	ng/mL
Vitamin B12	255	134	184	164	> 400	211 - 400	< 211	pg/mL
Magnesium	2.0	164	184	164	1.3 - 2.7	1.2 - <1.3	< 1.2 or > 5.1	mg/dL
Iron	48	164	134	184	65 - 175	49 - 64	< 49 or > 176	ug/dL
Ferritin	345	134	184	164	22 - 232	> 232 - 344	< 9.9 or > 344	ng/mL
Folate	5.00	134	184	164	> 5.39	3.38 - 5.39	< = 3.37	ng/mL
Free Fatty Acids	.5	134	184	164	<.60	.60 - .70	> = .70	mmol/L
Uric Acid	6.3	164	184	164	2.0 - 6.9	7	> = 8	mg/dL
PTH	234	164	134	184	<14.10	15 - 72	> 72	pg/mL

Stress & Inflammation

Test	02/02/2015	Historical Results 00/00/0000	00/00/0000	Baseline 00/00/0000	Optimal	Intermediate	High Risk	Unit
LpPLA2	220	134	184	164	< 200	200 - 235	> 235	ng/dL
hsCRP	1.20	134	184	164	< 1	1.0 - 2.9	> = 3	mg/L
Fibrinogen	395	164	184	164	126 - 390	390 - 517	< 126 or > 517	mg/dL
Homocysteine	30	164	134	184	> = 30	11 - 29	< = 10	µmol/L
NT-proBNP	128	134	184	164	< 125	125 - 449	> = 450	pg/mL
Galectin 3	220	134	184	164	< 200	200 - 235	> 235	ng/dL
MPO	1.20	134	184	164	< 1	1.0 - 2.9	> = 3	mg/L

Omega 3

Test	02/02/2015	Historical Results 00/00/0000	00/00/0000	Baseline 00/00/0000	Optimal	Intermediate	High Risk	Unit
Omega 3	220	134	184	164	< 200	200 - 235	> 235	ng/dL

Collection Date: 12/19/2014
Received Date: 12/19/2014
Report Date: 12/19/2014

Specimen ID: A1412190008
Lab Director: Kent R. Mitchell, Ph.D.
Report Type: Final

CLIA No. 45D2082195 | NPI No. 1619376316
Printed: 12/19/2014 16:13

Laboratory Test Results

TRUE HEALTH DIAGNOSTICS
EMPOWERING HEALTH THROUGH INSIGHT

6170 Research Road, Frisco, TX 75033
Phone or Fax: 866-953-2553

Account Information	
Account No	TXTHD0175033
Physician	Kent Mitchell Ph.D.
Practice	True Health
NPI	1619376316
Address	6170 Research Road Frisco, TX 75033

Patient Information	
Name	Man, Iron C.
Phone	(123) 456-7890
Sex	Male
DOB	01/01/1911
Specimen ID	A1412190008
BMI	30

Molecular/DNA **

Test	Purpose	Normal Risk	Intermediate Risk	High Risk
ApoE Genotype C112R R158C	Hyper Lipemia	E3/E3		
MTHFR C677T (Methylenetrahydrofolate Reductase)	Hyper Homocysteinemia		C/T	
MTHFR A1298C	Hyper Homocysteinemia	A/A		
Factor V Leiden G1691A	Thrombophilia	G/G		
Prothrombin Factor II G20210A	Thrombophilia			G/A

Pharmacogenomics/DNA **

Test	Purpose	Normal Risk	Intermediate Risk	High Risk
CYP2C19 Genotype	Pavix Dosing	*1/*1		
CYP2C9 Genotyping *2/*3	Warfarin Dosing			MUT/WT
VKORC1 Genotyping G1639A	Warfarin Dosing	SUT		

*This test was performed by Lipo Science 2500 Sumner Blvd, Raleigh NC 27616 CLIA 34D0952253

** The Genetic/DNA testing above was developed and its functioning qualities esablished by True Health Diagnostics, LLC. This test has not been approved or cleared by the U.S. Food & Drug Administration (FDA). The FDA has concluded that such clearance or approval is not necessary. This laboratory is certified under CLIA '88 as qualified to perfom high complexity clinical laboratory testing. All genetic tests performed at True Health Diagnostics using TIB MOLBIOL LightCycle reagents greater than 99% accurate. Note: Non carrier = Normal.

Laboratory Test Results

TRUE HEALTH DIAGNOSTICS
EMPOWERING HEALTH THROUGH INSIGHT

6170 Research Road, Frisco, TX 75033
Phone or Fax: 866-953-2553

Account Information	
Account No	TXTHD0175033
Physician	Kent Mitchell Ph.D.
Practice	True Health
NPI	1619376316
Address	6170 Research Road Frisco, TX 75033

Patient Information	
Name	Man, Iron C.
Phone	(123) 456-7890
Sex	Male
DOB	01/01/1911
Specimen ID	A1412190008
BMI	30

Hormones

Test	02/02/15	Previous	Flag	Reference Range
Total Testosterone	500		LOW	300 - 1200
SHBG	140.00		LOW	27.90 - 146.00
Free Testosterone	.40		LOW	.10 - .85
DHEA-S	30		LOW	25.90 - 568.90
PSA	2		LOW	0.00 - 4.00
FSH	33.0		LOW	1.5 - 33.4
LH	50		LOW	0.5 - 76.3
Progesterone	.20		LOW	0.15 - 28.00
Estradiol	40		LOW	20 - 144
Prolactin	2		LOW	2.80 - 29.20

Thyroid

Test	02/02/15	Previous	Flag	Reference Range
TSH	1.900		LOW	0.550 - 4.780
T3	88.0		LOW	60.00 - 181.00
T4	8		LOW	4.5 - 10.9
Free T3	3		LOW	2.3 - 4.2
Free T4	1.50		LOW	0.89 - 1.76
TPO Ab	5		LOW	0.00 - 60

Hepatic

Test	02/02/15	Previous	Flag	Reference Range
TP	7		LOW	5.7 - 8.2
ALB	4		LOW	3.4 - 5.4
TBili	-1		LOW	-3 - 1.2
DBili	.05		LOW	0.00 - 0.20
ALK	60		LOW	45 - 129
AST	3		LOW	0 - 34
ALT	11		LOW	10 - 49

Renal

Test	02/02/15	Previous	Flag	Reference Range
ALB	4.5		LOW	3.4 - 5.4
BUN	15		LOW	9.0 - 23
Creat	1.0		LOW	.7 - 1.3
Cystatin-C	0.92		LOW	.95 - 10.4
Ca	8.9		LOW	8.7 - 10.4
CO_2	32		HIGH	20 - 31
Gluc	80		LOW	60 - 100
PO_4	7		HIGH	2.4 - 5.20
K	4.00		LOW	3.5 - 5.50
NA	131		LOW	132 - 146
CL	112		HIGH	99 - 109

Laboratory Test Results

TRUE HEALTH DIAGNOSTICS
EMPOWERING HEALTH THROUGH INSIGHT

6170 Research Road, Frisco, TX 75033
Phone or Fax: 866-953-2553

Account Information

Account No	TXTHD0175033
Physician	Kent Mitchell Ph.D.
Practice	True Health
NPI	1619376316
Address	6170 Research Road Frisco, TX 75033

Patient Information

Name	Man, Iron C.
Phone	(123) 456-7890
Sex	Male
DOB	01/01/1911
Specimen ID	A1412190008
BMI	30

CMP

Test	02/02/15	Flag	Referance Range
ALB	5.6	LOW	3.4 - 5.4
ALK	70	LOW	45 - 129
ALT	12	LOW	10 - 49
AST	32	LOW	0 - 34
BUN	22.0	LOW	9.0 - 23.0
Creat	1.2	LOW	0.7 - 1.3
Ca	8.9	LOW	8.7 - 10.4
CO_2	23.0	LOW	20.0 - 31.0
Cl	102	LOW	99 - 109
Gluc	98	LOW	60 - 100
K	4.00	LOW	3.50 - 5.50
Na	135	LOW	132 - 146
TBili	.3	LOW	.3 - 1.2
TP	5.9	LOW	5.7 - 8.2 mg/dL

BMP

Test	02/02/15	Flag	Reference Range
BUN	22.0	LOW	9.0 - 23.0
Creat	1.2	LOW	0.7 - 1.3
Ca	8.9	LOW	8.7 - 10.4
CO_2	19	LOW	20.0 - 31.0
Cl	102	LOW	99 - 109
Gluc	98	LOW	60 - 100
K	3.5	LOW	3.50 - 5.50
Na	135	LOW	132 - 146

CBC w/ Diff

Test	02/02/15	Flag	Reference Range
WBC	6.1	LOW	3.98 - 10.04
RBC	4.80	LOW	3.93 - 5.22
HGB	14.2	LOW	11.2 - 15.7
HCT	43.7	LOW	34.1 - 44.9
MCV	91	LOW	79.4 - 94.8
MCH	29.6	LOW	25.0 - 32.0
MCHC	32.5	LOW	32.0 - 37.0
RDW-CV	13.8	LOW	11.6 - 14.4
RDW-SD	46	LOW	35.0 - 46.0
PLT	187	LOW	182 - 369
NEUT%	37.2	LOW	34 - 71
LYMPH%	34.5	LOW	19.3 - 53.1
MONO%	19.6	HIGH	4.7 - 12.5
EO%	2.8	LOW	0.7 - 7.0
BASO%	.08	LOW	0.1 - 1.2
NEUT#	2.26	LOW	1.56 - 6.13
LYMPH#	2.10	LOW	1.18 - 3.74
MONO#	1.19	HIGH	0.24 - 0.82
EO#	0.17	LOW	0.04 - 0.54
BASO#	0.05	LOW	0.01 - 0.08
IG%	5.10	HIGH	0.11 - .33
IG#	0.31	LOW	0.0 - 1.0
NRBC%	0.0	LOW	0 - 0
NRBC#	0	LOW	0 - 0

Collection Date: 12/19/2014
Received Date: 12/19/2014
Report Date: 12/19/2014

Specimen ID: A1412190008
Lab Director: Kent R. Mitchell, Ph.D.
Report Type: Final

CLIA No. 45D2082195 | NPI No. 1619376316
Printed: 12/19/2014 16:13

Laboratory Test Results

TRUE HEALTH DIAGNOSTICS
EMPOWERING HEALTH THROUGH INSIGHT

6170 Research Road, Frisco, TX 75033
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Account Information	
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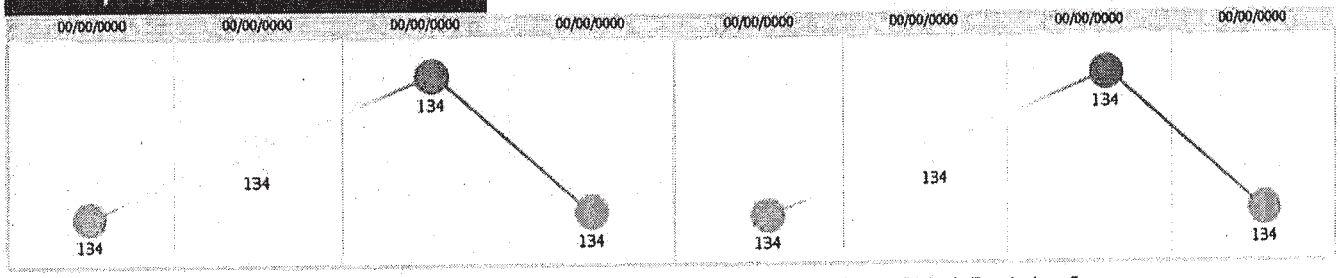
Practice	True Health
NPI	1619376316
Address	6170 Research Road Frisco, TX 75033

Patient Information	
Name	Man, Iron C.
Phone	(123) 456-7890
Sex	Male
DOB	01/01/1911
Specimen ID	A1412190008
BMI	30

Graph Results



Cardiac Framingham Score

Diabetic Framingham Score

Exhibit 6

TRUE HEALTH DIAGNOSTICS

6170 Research Rd. #211 Frisco, TX 75033
Phone/Fax (866) 953-2553
Email: customersupport@truehealthdiag.com

Account Executive: KEVIN / KYLE
Sign up Date: 03/05/2015
Implementation Date: 03/09/2015

Account Information: ☒ New ☐ Change

Practice Name: _____ Phone: (____) ____-____ Fax: (____) ____-____

Address: _____ City: _____ State: ____ Zip: _____

Key Contacts:

Office Manager: _____ Cell Ph: (____) ____-____ Critical Values Contact: _____ Cell Ph: (____) ____-____

↳ Ok to contact after hours ☐ Yes ☐ No

Open Arms Medical Center
Family Medicine

Brian Creghan, (M.D.), MBBS, PA-C
Bart Gershenbaum, D.O.
John Larsen, M.D.
James O'Connor, MPH, PA-C

6435 SE Hwy 301 352-481-5700
Hawthorne, Fl 32640 fax: 352-481-5750

(IN, etc)	Email	Cell	Circle access
			PORTAL PST
			PORTAL PST
			PORTAL PST
			PORTAL PST
			PORTAL PST
			PORTAL PST

☒ Advanced Diagnostics

☐ Patient Selection Tool (PST)
Billed at $_____ per _____ Doctor Initials: _____

Doctor and Staff signed off on implementation Date? (Y) / N

Number of patients scheduled for implementation: _____

Placing Phlebotomist or Practice Draw? Placement (Staff)

Name of Practice Phlebotomist: _____

Phlebotomist Cell Phone: (____) ____-____

How Does the Account want to Receive Reports?

☒ FedEx Overnight No. of copies: 2

☐ Provider Portal - email: _____

☒ Fax (Black & White) (352) 481-5950

Equipment: Initial Supply Shipment (indicate quantity)

Initial Supply Shipment to be sent to:	office	AE
[50] Requisitions	☐	☒
[5/5] Specimen Mail-In Kits 5 single / 5 large	☐	☒
[ ] Extra Patient Specimen Bags with Tubes	☐	☐
[1] Clinic Welcome Binder	☐	☒
[50] Patient Billing Information Cards	☐	☒
[1] Patient Selection Tool Device	☐	☒

Custom Orders: Check all that apply, indicating "Baseline" (B/L) and/or "Follow Up" (F/U). Circle individual tests if entire panel not desired.

B/L	F/U	
☐	☐	Advanced CVD Monitoring: Lipid Panel, HDL P via NMR, Apo-B, Apo-A-1, Lp(a), sdLDL, HDL-P via NMR, HDL Size
☐	☐	Stress and Inflammation: NT-proBNP, Lp-PLA2, hs-CRP, Homocysteine, Fibrinogen, Galectin-3
☐	☐	Diabetic / Prediabetic: Glucose, GlycoMark, Fructosamine, HgbA1c, Insulin, C-peptide, Adiponectin, Leptin, Cortisol, Quantose IR, Quantose IGT
☐	☐	Metabolic: 25-OH Vitamin D, Vitamin B12, Folate, Iron, Ferritin, Cystatin-C, Free Fatty Acids, Uric Acid, PTH
☐		Molecular / DNA: Factor V, Factor II, MTHFR, ApoE Genotyping
☐		Pharmacogenomics/DNA: CYP2C19, CYP2C9, VKORC1
☐	☐	Advanced Stress & Inflammation: Troponin I, IL-6, IL-17A, TNF-α, VEGF
☐	☐	Male Hormones: Testosterone (Free & Total), SHBG, DHEA-S
☐	☐	Female Hormones: Testosterone (Total), FSH, LH, Progesterone, Estradiol, DHEA-S, Prolactin
☐	☐	Thyroid Function: TSH, FT3, T4, Free T3, Free T4, TPO Ab
☐	☐	Hepatic Function: TP, ALB, Tbili, Dbil, ALK, AST, ALT
☐	☐	Renal Function: ALB, BUN, Creat, Ca, CO_2, Cl, PO_4, K, Na
☐	☐	CMP: ALB, ALK, ALT, AST, Bili, Creat, Ca, CO_2, Cl, Glu, K, Na, Tbil, TP
☐	☐	BMP: BUN, Creat, Ca, CO_2, Cl, Gluc, K, Na
☐	☐	CBC
☐	☐	CBC w/Diff
☐	☐	Miscellaneous: (Please Circle) CoQ10, Omega 3 & 6, PSA
☐	☐	Other Tests: _____

Signature of Lead Provider: I request and authorize True Health Diagnostics LLC to perform the above listed tests and to retain my signature on file for future use on orders received from this practice. I understand and agree that I have determined that all tests ordered are medically necessary for me, and that I may change this order or any individual order at any time. I acknowledge that True Health will retain ownership of any results generated as our facility for purposes of services provided by True Health and will only be used for those purposes. I further agree that it is the intent of both parties to comply with all federal, state, or local laws and that I have received no incentive to perform laboratory services from True Health Diagnostics.

X _____ 03/09/15

Proprietary and Confidential

① PLEASE SEND TO PAOLO SALVADOR
** NO TO OFFICE **
** NO LATER THAN 03/09/2015 AM

② PLEASE CREATE REQS USING WHITE SHEET FORMAT

Exhibit 7

PART II

POLICIES AND PROCEDURES FOR INDEPENDENT LAB SERVICES PROGRAM

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

DIVISION OF MEDICAID

Published: October 1, 2015

PART II – POLICIES AND PROCEDURES FOR INDEPENDENT LABORATORY SERVICES

CONTENTS

PART II - CHAPTER 600

SPECIAL CONDITIONS OF PARTICIPATION

601. In addition to the general conditions of participation identified in Part I, Section 106, providers in the Independent Laboratory Program must meet the following conditions:

601.1 Agree to operate independent of both the attending or consulting physician's office and of a hospital which meets at least the requirements specified in section 1861(e) and (j) of the Act to qualify for payment for emergency hospital services under Section 1814(d) of the Act.

601.2 Be established as a single facility for the biological, microbiological, serological, immunological, chemical, hematological, radiobioassay, cytological, pathological or other examination of materials derived from the human body, for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or assessment of a medical condition. Facilities that only collect specimens and do not perform testing are excluded from participation in the Medicaid Laboratory program.

601.3 Agree to bill the Division only for services rendered in those specialty areas for which current certification has been granted by the Department of Health and Human Services (DHHS).

601.4 Agree to maintain current State licensure (if required by the state in which the laboratory is located), and to supply the Division with copies of such, and to immediately notify the Division in writing of revocation, suspension or change in licensure.

601.5 Agree to bill the Division for only those laboratory services and/or procedures that are completed within that facility. The Division will also cover laboratory services performed at one location within the same hospital system even though the specimen was collected at another location within the same hospital system. Under no circumstances may laboratory services rendered by another laboratory that are NOT within the same hospital system or laboratory site, physician or group practice be billed to the Division. Independent laboratories must comply with all Conditions of Participation outlined in Chapter 600 and Part II of the Policies and Procedures of the Independent Laboratory Services Manual.

601.6 Be certified for participation in the Title XVIII, Part B, Medicare Program.

601.7 Agree to bill only for laboratory services requested by an attending or consulting physician or podiatrist.

601.8 Agree to maintain copies of the requesting physician's request slip and the test results for a period of five (5) years. The records for pathology test reports must be maintained for a period of ten years and records of blood product testing and immunology for a period of not less than five (5) years, according to federal law. Records shall be retained in the laboratory in such a manner that permits ready identification and accessibility.

601.9 Agree to bill the Division the lowest rate charged to private patients, other third party payers and insurance carriers, health maintenance organizations or other members of the general public for comparable services. The lowest rate includes any special price or discounts offered to such patients.

601.10 Agree to notify the Division's Provider Enrollment/Reference Data Base Unit in writing should any change in enrollment status occur such as: new address or telephone number, additional locations, or voluntary termination. Each notice of change must include the date on which the change shall be effective.

601.11 Comply with the existing regulatory programs covered by federal, state, and local laws for fire safety, environment and health-related matters.

601.12 Enroll and successfully participate in a proficiency testing program approved by DHHS for each specialty and subspecialty in which the laboratory seeks Medicare approval or licensure under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 or both. Failure to successfully participate in a proficiency testing program will result in the termination of the laboratory from the Medicaid program.

601.13 Submit to the Division Provider Enrollment/Reference Data Base Unit a completed copy of the Disclosure of Ownership Form (CMS 1513).

PART II - CHAPTER 700

SPECIAL ELIGIBILITY CONDITIONS

701. In addition to those eligibility conditions described in Part I, Section 102, members receiving services under this Program must be referred, in person or by delivery of specimen, by a physician or podiatrist. The laboratory must have a valid laboratory request slip from the referring provider indicating the tests to be performed.

PART II - CHAPTER 800

PRIOR APPROVAL

801. The services covered in this manual do not require prior approval. However, the Division may require prior approval of all or certain procedures performed by a laboratory based on the findings or recommendations of the Division, its authorized representatives or agents, the Secretary of the U.S. Department of Health and Human Services or the applicable State Licensing Agent. This action may be invoked by the Commissioner as an administrative recourse in lieu of or in conjunction with an adverse action described in Chapter 400. In such instances, the Department will serve written notice to the provider of this requirement and the grounds for such action.

SCOPE OF SERVICES

PART II - CHAPTER 900

901. General

The Independent Laboratory program reimburses for most pathological and clinical laboratory tests, subject to the service limitations described in Section 903 and the non-covered services described in Section 904. All services are subject to these limitations without regard to diagnosis, type of illness, or condition.

902. Coding

Provider coding of both diagnosis and procedures is required for all claims. The coding schemes acceptable by the Division are the ICD-10-CM (International Classification of Diseases - 10th Edition - Clinical Modification) for diagnoses and the CPT (Current Procedural Terminology- 4th Edition) for procedures. Copies of the CPT and ICD-10-CM code books are available for purchase from the following organizations:

CPT	ICD-10-CM
American Medical Association Order Department OP341-6 Post Office Box 10946 Chicago, Illinois 60610	ICD-10-CM Post Office Box 991 Ann Arbor, Michigan

Certain codes from these coding schemes are not accepted by the Division and are discussed in the following sections:

902.1 ICD-10-CM

Codes deleted from previous editions of the ICD are not accepted by the Division. The ICD-9-CM (ICD-10-CM) coding scheme consists of three volumes. Only Volumes I and II are needed by independent laboratories. Further, the special categories of ICD-9 codes which begin with alphabetic characters "E" (E800 - E999) and the corresponding ICD-10 codge range that begin with V81.2XXZ – Y36.0105 are not accepted by the Division. The remaining special category of codes which begin with "V" or "Z"are acceptable only if the "V" or "Z"code describes the primary diagnosis. The provider must select the diagnosis codes which most nearly describes the diagnosis of the patient.

In coding the diagnosis on your claims, the code must be placed on the claim form using the identical format (including the decimal point) as

shown in the ICD-9-CM (examples: 402; 402.0; 402.00) and the ICD-10-CM codes, effective on and after October 01, 2015 (examples: I11, I11.0 and I11.9). Coding must be to the lowest level.

It is the responsibility of the laboratory to obtain the member's diagnosis from the prescribing practitioner at the time the referral is made.

902.2 CPT

Laboratory procedures are defined in the CPT in the ranges 80047 through 89356. Providers must select the procedure code(s) that best describes the procedure(s) performed. The following instructions apply to the use of the CPT procedure codes on laboratory claims:

a) Codes deleted from previous editions of the CPT are not reimbursable;

b) Most of the codes for "Unlisted Procedures" which end in "99" are not accepted by the Division;

c) The 26 and TC modifiers should be used only when necessary; other modifiers used for clarifying circumstances are not accepted by the Division.

d) The appropriate "Place of Service" codes located on the back of the CMS-1500 claim form must be used.

e) Updates to the CPT are effective as soon as possible after the month of publication. This applies to deletions, additions and/or revisions. It is the laboratory staff's responsibility to maintain an up-to-date CPT publication.

903. Service Limitations

903.1 Specimen Conveyance to another Laboratory

Specimen conveyance from one independent laboratory to another independent laboratory or to one of the Public Health Laboratories is not reimbursable.

903.2 Automated Chemistries (Bundling and Unbundling)

Individual components of automated, multi-channel tests must be billed separately. These tests must be billed using codes in the ranges 80047 through 89356 and 80047 through 80076.

a. When any of the twenty three automated tests are performed:

1. Bill the CPT for each individual test, or
2. Bill the CPT for the Organ Disease Panel (OD) plus the individual CPT code for any automated tests not included in the panel.

b. When several panels are ordered that contain some or all of the same automated chemistries, payment will be equal to the total number of different automated chemistries in all of the panels (minus any duplicate tests). Multiples of OD panels may be denied.

c. When any of the twenty-three automated chemistries are part of an OD panel, payment for the OD panel will be made if the panel contains only the automated tests for that date of service for that member.

d. When other automated chemistries are ordered along with the OD panel, the panel will be unbundled and a fee based on the least expensive method of grouping the automated chemistries and OD panel.

903.3 Public Health Laboratory Services

The following policies and procedures on Public Health Laboratory services must be followed:

Effective July 1, 2010, Fee for Service (FFS) Medicaid will begin reimbursing providers the $10 lab handling fee assessed by the GPHL. The $10.00 reimbursement is limited to CPT lab codes:

CPT 83655—Assay of lead

CPT 86803—Hepatitis C AB test

Providers are also required to continue to submit all other specified lab tests to the GPHL, as outlined in the Part II Policy and Procedure for Independent Laboratory Services, Section 903. Only CPT codes 83655, 86403, 86689, and 86803 are subject to reimbursement.

To ensure accurate reimbursement, providers must submit CPT codes 83655, 86403, 86689, and 86803 with modifier 90 or 91, on the CMS 1500 claim form per established billing guidelines.

Modifier 90—Reference (Outside) Laboratory: When laboratory procedures are performed by a party other than the treating or reporting physician, the procedure may be identified by adding modifier 90 to the usual procedure number.

Modifier 91—Repeat Clinical Diagnostic Laboratory Test: In the course

of treatment of the patient, it may be necessary to repeat the same laboratory test on the same day to obtain subsequent (multiple) test results.

Newborn Screens

Rev 04/14

The following follow up tests are allowed on infants less than three (3) months of age when the initial screenings is positive. These claims must be billed with diagnosis code ICD 9 CM 796.6 (ICD 10 CM P09). However, the neonatal metabolic screens are required by the State on all infants between 24 hours after birth or by the seventh day of life. The initial screening specimen shall continue to be sent on filter paper (DHR Form 3491) to the Public Health Laboratory, Central Facility in **Atlanta** only.

Rev 12/08

Procedure Codes 82016 82017 82127 82131 82261
82776 83020 83498 83788 83789
84030 84436 84437 84442 84443
84150

Specimens for the above battery of tests may be on a full blood sample (not filter paper) and must be performed by any CLIA certified participating laboratory.

Hemoglobin Testing

Rev 04/14

The Division will not make payment for the following test for sickle cell detection, confirmation or follow-up for infants and family members of infants suspected of sickle cell anemia or trait. Diagnosis codes include ICD 9 CM 282.60- 282.69 (ICD 10 CM D57.1 through D57.812).

83020 include SS, SC, SE, S Beta Thalassemia, SO, and SD.

All blood specimens with a sickle cell indicator must be forwarded in an appropriate sickle cell outfit to the Waycross Regional Public Health Laboratory.

The Division will provide reimbursement for hemoglobin tests for possible diagnosis other than sickle cell.

Gonorrhea and Syphilis Testing

The Department will not provide reimbursement for diagnosis ICD 9 CM 098-099.9 (ICD 10 CM A54 through A64) with the following procedure codes:

Rev 04/14

Procedure codes

87070 87081 87205

All blood/serum specimens for gonorrhea and syphilis must be routed in outfits provided by the State laboratory. Specimens for RPR's may be routed to any of the two State laboratories. Specimens for VDRL's and FTA's must be routed to the laboratory in Atlanta only.

Patients requiring dark field exams must be referred to their local Health Department.

Tuberculosis Testing

Rev 04/14

The following procedures are for tuberculosis diagnosis ICD 9 CM 010-017.0 (ICD 10 CM A15.0 through A15.9 & A18.4) testing:

87116 87118

All sputums with a tuberculosis indicator must be forwarded in the sputum outfit provided by the State to the State laboratory in Atlanta only. **Under no condition will the Division reimburse for tuberculosis testing.**

Salmonella and Shigella Testing

Rev 04/14

Diagnoses included are ICD 9 CM 003 or 004-004.9 (ICD 10 CM A02.0 – A03.9).

The procedures are: 87045, and 87081.

Stool culture (87045) is often used for the detection of salmonella and/or shigella. Therefore, all stool cultures with a salmonella or shigella indicator must be forwarded in a stool culture outfit (provided by the State) to the State laboratory in Atlanta. Under no condition will the **Division reimburse** for salmonella or shigella testing.

Effective March 1, 2002, the following tests are restricted to the State laboratory:

86318	86403 (syphilis only)	87253	86689 (HIV only)
87116	87118	87390	87252

The State laboratory locations and telephone numbers are listed below: **Please include the member's Medicaid Number above their name on the specimen requisition form. The member must be eligible for Medicaid services on the date services are rendered.**

1. Decatur Central Public Health Laboratory

   Georgia Department of Public Health
   Laboratory Services & Supply
   1749 Clairmont Road
   Decatur, Georgia 30033-4050
   (404) 327-7920 FAX (404) 327-7922

2. Waycross Public Health Laboratory

   Georgia Department of Public Health
   Laboratory Services & Supply
   1751 Gus Karle Parkway
   Waycross, Georgia 31503
   (912) 338-7050 FAX (912) 338-7061

Specimen outfits for testing to be done in the Regional Laboratories are available from the preceding addresses; however, the outfits for the tests in the Central Facility must be obtained from:

Laboratory Services and Supply
1749 Clairmont Road
Decatur, Georgia 30033-4050
(404) 327-7920 FAX (404) 327-7922

903.4 Hemodialysis Related Testing

Laboratory procedures performed as part of routine hemodialysis services rendered in a dialysis center will not be separately reimbursed without medical documentation.

The following list identifies laboratory tests that can be reimbursed routinely without documentation of medical necessity when the diagnosis code is end stage renal disease. If the procedures are performed at a frequency greater than that specified below, they are covered only if accompanied by medical documentation. For reimbursement of procedure codes performed outside of the frequencies below, the provider must send to the Medical Review Unit a copy of the remittance advice notice with the denied service, a completed CMS-1500 claim form, and documentation from the ordering provider the medical necessity to support the need for the tests. This documentation must include information other than the physician's order and medical diagnosis of the member. The diagnosis code indicating ESRD alone is not sufficient.

(a) Testing for hepatitis B Surface Antigen (Hbsag), procedure code 87340 is limited to one month for patients who are identified as seronegative.

(b) Hepatitis B Surface Antibody or Hepatitis B Core Antibody testing is limited to one but not both, once a year. Procedures included are: 86704, 86705, 86706, and 87350; and

(c) Serum aluminum (82108) and Serum Ferritin (82728) are limited to one every 3 months.

903.5 Laboratory Test Included In The Dialysis Fee

The tests listed below are restricted when the procedures are performed in conjunction with dialysis. The procedures listed below are included in the dialysis fee and are not directly reimbursable to the laboratory.

82042 Albumin, Urine
82247 Bilirubin, total
82248 Bilirubin, direct
82310 Calcium, total
82330 Calcium, iodized
82734 CO2 Combining Power
82435 Chloride, Serum
82436 Chloride, Urine
82540 Creatine, Blood
82565 Creatinine, Blood
82575 Creatinine, Clearance
82947 Glucose, Serum
83615 LDH, Blood
83735 Magnesium, Serum, Chemical
84075 Alk, Phosphatase
84100 Phosphorus (phosphate), Serum

84105 Phosphorus (Phosphate), Urine
84132 Potassium; Serum, plasma or whole blood
84133 Potassium, Urine
84155 Protein, total, except by refractometry; serum, plasma or whole blood
84295 Sodium; Serum, plasma or whole blood
84300 Sodium, Urine
84450 SGOT
84460 SGPT
84520 BUN
84550 Uric Acid, Blood
84560 Uric Acid, Urine
85014 Hct.
85018 Hgb.
85025 CBC
85027 CBC with platelet count
85041 RBC
85048 WBC
85610 Prothrombin Time

Note: Procedures codes shown above include any other lab code with similar descriptions.

903.6 Specimen Collecting Fee (Venipuncture or Catheter Urine)

The collection of specimen associated with dialysis laboratory tests is included in the dialysis fee and is non-covered.

Rev. 01/15

903.7 Drug Testing

Drug procedures are divided into three subsections: Therapeutic Drug Assay, Drug Assay, and Chemistry – with code selection dependent on the purpose and type of patient results obtained. Therapeutic Drug Assays are performed to monitor clinical response to a known, prescribed medication. The two major categories for drug testing in the Drug Assay subsection are:

Presumptive Drug Class procedures are used to identify possible use or non-use of a drug or drug class. A presumptive test many be followed by a definitive test in order to specifically identify drugs or metabolites.

Definitive Drug Class procedures are qualitative or quantitative tests to identify possible use or non-use of a drug. These tests identify specific drugs and associated metabolites, if performed. A presumptive test is not required prior to a definitive drug test.

Presumptive Drug Class Screenings are drugs or classes of drugs may be commonly assayed first by presumptive screening method followed by a definitive drug identification method. The list of drug classes and the methodology are considered when coding presumptive procedures. If a drug class is not listed in List A or List B and it is not performed by **Thin-Layer Chromatography (TLC),** use 80304 unless the specific analyte is listed in the Chemistry Section.

Drug Class List A

The following list contains drugs or classes of drugs that are commonly assayed by presumptive procedures. The methodology is typically one in which the results are capable of being read by direct optical observation, including instrument-assisted when performed, or by instrumented test systems. These procedures may also be followed by a definitive procedure.

- Alcohol (Ethanol)
- Amphetamines
- Barbiturates
- Benzodiazepines
- Buprenorphine
- Cocaine metabolite
- Heroin metabolite (6-monoacetylmorphine)
- Methadone
- Methadone metabolite (EDDP)
- Methamphetamine
- Methaqualone
- Methylenedioxymethamphetamine (MDMA)
- Opiates
- Oxycodone
- Phencyclidine
- Propoxphene
- Tetrahydrocannabinol (THC) metabolites (marijuana)
- Tricyclic Antidepressants

Drug Class List B

The following list contains drugs or classes of drugs that may be assayed by presumptive procedures. The methodology typically requires more resources that the drugs listed in Drug Class List A. The procedure may include drug class specific preanalytical sample preparation. It may be manual process such as ELISA.

- Acetaminophen
- Carisoprodol/Meprobamate
- Ethyl Glucuronide
- Fentanyl
- Ketamine
- Meperidine
- Methlphenidate
- Nicotine/Cotinine
- Salicylate
- Synthetic Cannabinoids
- Tapentadol
- Tramadol
- Zolpidem
- Not otherwise specified

Definitive Drug Testing

Definitive drug identification methods are able to identify individual drugs and distinguish between structural isomers but not necessarily stereoisomers. Definitive methods include, but are not limited to, gas chromatography with mass spectrometry and liquid chromatography mass spectrometry and exclude immunoassays and enzymatic methods. The Definitive Drug Classes Listing provides the drug classes, their associated CPT codes, and the drugs included in each class. Each category of a drug class, including metabolite(s) if performed (except stereoisomers), is reported once per date of service. Metabolites not listed in the table may be reported using the code for the parent code for the parent drug. Drug class metabolite(s) is listed as a separate category in Definitive Drug Classes Listing.

The code is based on the number of reported analytes and not the capacity of the analysis.

Specimen outfits for testing to be done in the Regional Laboratories should be ordered directly from those laboratories at the below listed address.

The State Laboratory locations and telephone numbers are listed below:

Decatur Central Public Health Laboratory
Georgia Department of Public Health
Laboratory Services & Supply
1749 Clairmont Road
Decatur, Georgia 30033-4050
(404) 327-7920 FAX (404) 327-7922

Waycross Public Health Laboratory
Georgia Department of Public Health
1751 Gus Karle Parkway
Waycross, Georgia 31503
(912) 338-7050 FAX (912) 338-7061

903.8 HIV Screening Testing

The Division reimburses for screening tests when ordered by the member's physician or practitioner within the context of a healthcare setting and performed by an eligible Medicaid provider.

The following procedures are for HIV screenings:

86701 Analysis for antiboby to HIV -1 virus
86702 Analysis for antiboby to HIV- 2 virus
86703 Analysis for antiboby to HIV – 1 and HIV- 2 virus
87389 Detection test for HIV-1 and HIV-2
87390 Detection test for HIV-1
87391 Detection test for HIV-2

903.9 HIV Resistance Testing

(A) The Division reimburses for genotype assay and phenotype assay tests for the management of Human Immunodeficiency Virus (HIV) type I. These tests will help determine drug resistance or drug sensitivity and are useful for patients who are not improving on a specific drug regimen.

Genotype analysis identifies mutations that are associated with drug resistance and phenotype analysis measures the ability of the virus to grow in the presences of drugs under consideration by the physician.

Reimbursement will be made when resistance testing is recommended in the following situations:

- When a patient presents with virologic failure during Highly Active Antiretroviral Therapy; and
- When the patient has suboptimal suppression of viral load after initiation of antiretroviral therapy.

Reimbursement will not be considered:

- When the patient's plasma viral load is <1000 HIV copies/ML;
- After the discontinuation of drugs; and
- With chronic HIV infection prior to initiation of therapy.

The following procedures are for HIV resistance testing:

- 87901 – Genotype analysis
- 87903 – Phenotype analysis up to 10 drugs
- 87904 – Each additional drug, up to 5 drugs; use this code in conjunction with 87903
- 87900-Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics

The following procedure is for HIV detection testing:

Rev 10/15 903.10

87536 – Detection test for HIV-1 virus

Molecular Diagnostic Testing

Procedure codes in the range 81500-81512, 87481 and 87798 when greater than one unit of service is required and when medical necessity supports the procedures that normally receive a National Correct Coding Initiative exception will be considered for payment.

904. Non-Covered Services

The list below represents common procedures and settings in which services are non-covered. This list is not meant to be exhaustive but is indicative of non-covered services:

a) Procedures completed in laboratories operated as a part of a physician's private office (described in the Policies and Procedures for Physician Services);

b) Procedures completed in laboratories providing services to hospital patients, operating on the premises of a hospital that meets the definition of an emergency hospital (described in the Policies and Procedures for Hospital Services);

c) Procedures referred to another testing facility;

d) Experimental services or procedures or those not recognized by the United States Public Health Service as universally accepted procedures;

e) Procedures deleted from previous and current editions of the CPT and those shown as "Unlisted Procedure" which end in "99";

f) Professional interpretation for procedures normally interpreted by an attending practitioner;

g) Services and/or procedures performed without regard to the policies contained in this manual;

h) Services provided free-of-charge to Medicaid members by state or public laboratories;

i) The collection and handling of specimens sent to an independent laboratory for further distribution to another testing facility;

j) Laboratory test procedures included in the dialysis facility's composite rate;

k) Specimen collection and or handling fee (Venipuncture or Catherized Urine);

l) Services for which the performing provider does not have appropriate CLIA certification;

m) Reimbursement for more than twenty-five multiple drug screens per member per fiscal year; and

n) Reimbursement will not be made for more than five (5) quantitative drug screens to monitor prescribed medications without medical justification.

PART II - CHAPTER 1000

BASIS FOR REIMBURSEMENT

1001. Reimbursement Methodology

The Division will pay the lower of the laboratory's usual and customary charge, or the statewide maximum allowable amount for the procedure rendered. This maximum allowable amount is derived from an analysis of the usual and customary fees submitted for a given procedure. The Division cannot exceed the prevailing reimbursement rate that has been established for Medicare reimbursement for the same clinical laboratory procedure

The Schedule of Maximum Allowable Payments is not a fee schedule. As required in Section 601.8, providers must bill the Division their usual and customary fees. Providers must not change their fees to the rates in this Schedule, even if their fees are higher than those listed for the service rendered. Usual and customary fees are recorded and used by the Division when the Schedule of Maximum Allowable Payments is updated.

Multiple laboratory procedures billed for the same member should be submitted on one claim for that date of service.

1002. Co-payment

Members receiving services are not subjected to co-payment requirements. Independent Laboratory Services are exempt.

1003. CLIA Requirements

All providers that bill for laboratory services must have CLIA certification equal to the procedure code being billed. If a provider bills for a procedure without appropriate CLIA certification, reimbursement will be denied.

If multiple providers share a location that has a laboratory for that office/practice, all of the Medicaid providers at that location must have the CLIA number for that location on his/her individual provider file for billing. Please send all CLIA and provider information to the Provider Enrollment Unit.

It is not necessary to send procedure codes and certification areas to the Department any more.

If a procedure code is excluded from CLIA requirements, the provider will not be required to have any type CLIA certification.

Rev 04/13

1004. National Correct Cording Initiative (NCCI)

The Centers for Medicare and Medicaid Services (CMS) has directed all State Medicaid agencies to implement the National Correct Coding Initiative (NCCI) as policy in support of Section 6507 of the Patient Affordable Care Act of March 23, 2010.

Georgia Medicaid uses NCCI standard payment methodologies. NCCI Procedure to Procedure edits prevent inappropriate payment of services that should not be bundled or billed together and to promote correct coding practices. Based on NCCI Coding Manual and CPT guidelines, some services/procedures performed in conjunction with an evaluation and management (E&M) code will bundle into the procedure when performed by same physician and separate reimbursement will not be allowed if the sole purpose for the visit is to perform the procedures. NCCI editing also includes Medically Unlikely Edits (MUEs) which prevent payment for an inappropriate number/quantity of the same service on a single day. An MUE for a HCPCS/CPT code is the maximum number of units of service under most circumstances reportable by the same provider for the same patient on the same date of service. Providers must correctly report the most comprehensive CPT code that describes the service performed, including the most appropriate modifier when required.

For additional questions regarding the NCCI or MUE regulations, please see the CMS website: http://www.cms.gov/.

1005. General Claims Submission Policy for Ordering, Prescribing, or Referring (OPR) Providers

The Affordable Care Act (ACA) requires physicians and other eligible practitioners who order, prescribe and refer items or services for Medicaid beneficiaries to be enrolled in the Georgia Medicaid Program. As a result, CMS expanded the claim editing requirements in Section 1833(q) of the Social Security Act and the providers' definitions in sections 1861-r and 1842(b)(18)C. Therefore, claims for services that are ordered, prescribed, or referred must indicate who the ordering, prescribing, or referring (OPR) practitioner is. The department will utilize an enrolled OPR provider identification number for this purpose. Any OPR physicians or other eligible practitioners who are NOT already enrolled in Medicaid as participating (i.e., billing) providers must enroll separately as OPR Providers. The National Provider Identifier (NPI) of the OPR Provider must be included on the claim submitted by the participating, i.e., rendering, provider. If the NPI of the OPR Provider noted on the Georgia Medicaid claim is associated with a provider who is not enrolled in the Georgia Medicaid program, **the claim cannot be paid**.

Effective 4/1/2014, DCH will begin editing claims submitted through the web, EDI and on CMS-1500 forms for the presence of an ordering, referring or prescribing provider as required by program policy. The edit will be informational until 6/1/2014. Effective 6/1/2014, the ordering, prescribing and referring information will become a mandatory field and claims that do not contain the information as required by policy will begin to deny.

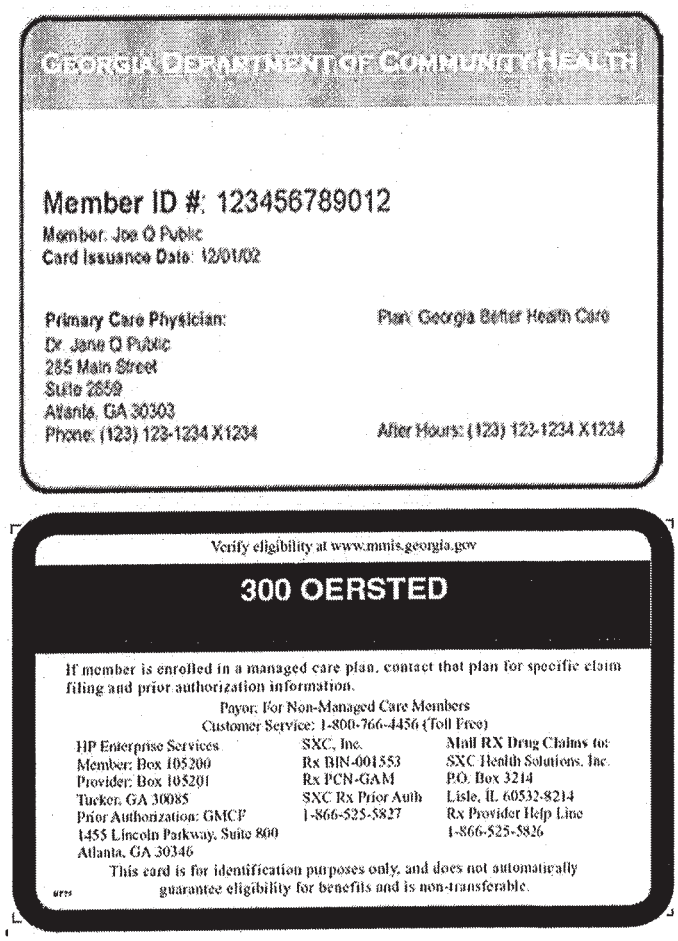
For the NEW CMS-1500 claim form:
Enter qualifiers to indicate if the claim has an ordering, referring, or prescribing provider to the left of the dotted line in box 17 (Ordering = DK; Referring = DN or Supervising = DQ).

For claims entered via the web:
Claims headers were updated to accept ordering or referring Provider ID and name for Dental and Institutional claims and the referring provider's name for Professional claims. The claim detail was updated to accept an ordering or referring provider ID and name. Utilize the "ordering" provider field for claims that require a prescribing physician.

For claims transmitted via EDI:
The 837 D, I, and P companion guides were updated to specifically point out the provider loops that capture the rendering, ordering, prescribing, referring and service facility provider information that is now used to transmit OPR information.

APPENDIX A

Sample Georgia Medicaid Card



APPENDIX B

STATEMENT OF PARTICIPATION

The new Statement of Participation is available in the Provider Enrollment Application Package via the web at www.mmis.ga.gov.

Phone your request to:

1 (800) 766-4456

APPENDIX C

BILLING INSTRUCTIONS AND CLAIM FORMS

Detailed information and instructions for completion and submission of claim forms can be found in this section. Claims must be filed on the required form with appropriate information in specific blocks for payment. Claim forms for Independent Laboratory Services are:

- Health Insurance Claim Form (CMS–1500)

  Claims must be submitted within (6) months from the month of service. Claim(s) with third party resource(s) must be submitted within (12) months from the month of service. Please refer to the Medicaid Secondary Claims User Guide for additional instructions.

- Medicaid-Medicare Crossover (CMS–1500)

  A special crossover claim form is no longer required when billing Medicaid/Medicare crossover. Claims must be submitted using the CMS–1500 format. This claim must have an Explanation of Medicare Benefits (EOMB) from Medicare for Medicaid payment. Claim (s) must be submitted within twelve (12) months from the month of service. Please refer to the Medicaid Secondary Claims User Guide for additional instructions.

The only significance differences using the new CMS-1500 claim form are items 20 and 23. For item 20, Georgia Medicaid does not allow Reference Lab billing or Outside Lab charges. Item 23, the CLIA number does not need to be inserted on the line item as CLIA information must be submitted to the Provider Enrollment Unit to be placed on the provider file.

PLACE OF SERVICE CODES

11 – Office

12 – Home

21 – Inpatient Hospital

22 – Outpatient Hospital

23 – Emergency Room - Hospital

24 – Ambulatory Surgical Center

25 – Birthing Center

26 – Military Treatment Facility (Not a covered POS for Georgia Medicaid

31 – Skilled Nursing Facility

32 – Nursing Facility

33 – Custodial Care Facility

34 – Hospice

41 – Ambulance – Land Maintenance

42 – Ambulance Air or Water

51 – Inpatient Psychiatric Facility

52 – Psychiatric Facility Partial Hospitalization (Not a covered POS for Georgia Medicaid)

53 – Community Mental health

TYPE OF SERVICE CODES

1 – Medical Care

2 - Surgery

3 – Consultation

4 – Diagnostic X-Ray

5 – Diagnostic Laboratory

6 – Radiation Therapy

7 – Anesthesia

8 – Assistance at Surgery

9 – Other Medical Service

0 – Blood or Packed Red Cells

A – DME

F – Ambulatory Surgical Center

H – Home Health

M – Alternate Payment For Dialysis

N – Kidney Donor

R – Rural Health/Community Health Ctr.

W – Nurse Midwife

Y – Second Opinion on Elective Surgery

Z – Third Opinion on Elective Surgery

PLACE OF SERVICE CODES CONT.

54 – Intermediate Care Facility/Mentally Retarded

(Not a covered POS for Georgia Medicaid)

56 – Psychiatric Residential Treatment Center

(Not a covered POS for Georgia Medicaid)

61 – Comprehensive Inpatient Rehabilitation Facility

62 – Comprehensive Outpatient Rehabilitation Facility

65 – End Stage Renal Disease Treatment Facility or Office

71 – State or Local Public Health Clinic

72 – Rural Health Clinic/Community Health Center

81 – Independent Laboratory

99 – Other

Rev 04/14 **NEW CMS 1500 Claim Form (version 02/12) & FLD Locator Instructions**

SIGNED
NUCC Instr

- The following table outlines the **revised changes** on the above CMS 1500 claim form version 02/12:

FLD Location	NEW Change
Header	Replaced 1500 rectangular symbol with black and white two-dimensional QR Code (Quick Response Code)
Header	Added "(NUCC)" after "APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE."
Header	Replaced "08/05" with "02/12"
Item Number 1	Changed "TRICARE CHAMPUS" to "TRICARE" and changed" (Sponsor's SSN)" to "(ID#/DoD#)."
Item Number 1	Changed "(SSN or ID)" to "(ID#)" under "GROUP HEALTH PLAN"
Item Number 1	Changed "(SSN)" to "(ID#)" under "FECA BLK LUNG."
Item Number 1	Changed "(ID)" to "(ID#)" under "OTHER.'
Item Number 8	Deleted "PATIENT STATUS" and content of field. Changed title to "RESERVED FOR NUCC USE."
Item Number 9b	Deleted "OTHER INSURED's DATE OF BIRTH, SEX." Changed title to "RESERVED FOR NUCC USE."
Item Number 9c	Deleted "EMPLOYER'S NAME OR SCHOOL." Changed title to "RESERVED FOR NUCC USE."
Item Number 10d	Changed title from "RESERVED FOR LOCAL USE" to "CLAIM CODES (Designated by NUCC)." **Field 10d is being changed to receive Worker's Compensation codes or Condition codes approved by NUCC.** **FOR DCH/HP:** FLD 10d on the OLD Form CMS 1500 Claim (08/05) will no longer support receiving the Medicare provider ID.
Item Number 11b	Deleted "EMPLOYER'S NAME OR SCHOOL." **Changed title to "OTHER CLAIM ID** (Designated by NUCC)". Added dotted line in the left-hand side of the field to accommodate a 2-byte qualifier
Item Number 11d	Changed "If yes, return to and complete Item 9 a-d" to "If yes, complete items 9, 9a, and 9d." (Is there another Health Benefit Plan?)
Item Number 14	Changed title to "DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP)." Removed the arrow and text in the right-hand side of the field. Added "QUAL." with a dotted line to accommodate a 3-byte qualifier." **FOR DCH/HP: Use Qualifiers: 431 (onset of current illness); 484 (LMP); or 453 (Estimated Delivery Date).**
Item Number 15	Changed title from 'IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS. GIVE FIRST DATE" to "OTHER DATE." Added "QUALIFIER." with two dotted lines to

	accommodate a 3-byte qualifier: 454 (Initial Treatment); 304 (Latest Visit or Consultation); 453 (Acute Manifestation of a Chronic Condition); 439 (Accident); 455 (Last X-ray); 471 (Prescription); 090 (Report Start [Assumed Care Date); 091 (Report End [Relinquished Care Date); 444 (First Visit or Consultation).
Item Number 17	Added a dotted line in the left-hand side of the field to accommodate a 2-byte qualifier – **Used by Medicare** for identifiers for provider roles: Ordering, Referring and Supervising. **FOR DCH/HP:** Use the following Ordering Provider, Referring, Supervising Qualifiers (**effective 4/01/2014**): **Ordering = DK; Referring = DN or Supervising = DQ.**
Item Number 19	Changed title from "RESERVED FOR LOCAL USE" to "ADDITIONAL CLAIM INFORMATION (Designated by NUCC)." **FOR DCH/HP:** Remove the Health Check logic from field 19 and add it in **field 24H.**
Item Number 21	Changed instruction after title (Diagnosis or Nature of Illness or Injury) from "(Relate Items 1, 2, 3 or 4 to Item 24E by Line)" to "Relate A-L to service line below (24E)."
Item Number 21	Removed arrow pointing to 24E (Diagnosis Pointer).
Item Number 21	Added "ICD Indicator." and two dotted lines in the upper right-hand corner of the field to accommodate a 1-byte indicator. Use the highest level of code specificity in FLD Locator 21. **Diagnosis Code ICD Indicator -** new logic to validate acceptable values (0, 9). ICD-9 diagnoses (CM) codes = value 9; or ICD -10 diagnoses (CM) codes = value 0. **(Do not bill ICD 10 code sets before October 1, 2015.)**
Item Number 21	Added 8 additional lines for diagnosis codes. Evenly space the diagnosis code lines within the field.
Item Number 21	Changed labels of the diagnosis code lines to alpha characters (A-L).
Item Number 21	Removed the period within the diagnosis code lines
Item Number 22	Changed title from "MEDICAID RESUBMISSION" to "RESUBMISSION." The submission codes are: 7 (Replacement of prior claim) 8 (Void/cancel of prior claim)
Item Numbers 24A – 24 G (Supplemental Information)	The supplemental information is to be placed in the shaded section of 24A through 24G as defined in each Item Number. F **FOR DCH/HP**: Item numbers **24A** & **24G** are used to capture Hemophilia drug units. **24H** (EPSDT/Family Planning).
Item Number 30	Deleted "BALANCED DUE." Changed title to "RESERVED FOR NUCC USE."
Footer	Changed "APPROVED OMB-0938-0999 FORM CMS-1500 (08/05)" to "APPROVED OMB-0938-1197 FORM 1500 (02/12)."

APPENDIX D

GEORGIA HEALTH PARTNERSHIP (GHP)

Electronic Data Interchange (EDI)

1-877-261-8785

- Asynchronous
- Web portal
- Physical media
- Network Data Mover (NDM)
- Systems Network Architecture (SNA)
- Transmission Control Protocol/Internet Protocol (TCP/IP)

Provider Inquiry Numbers:

800-766-4456 (Toll free)

The web contact address is www.mmis.georgia.gov

Appendix E

Non-Emergency Transportation

People enrolled in the Medicaid program need to get to and from health care services, but many do not have any means of transportation. The Non-Emergency Transportation Program (NET) provides a way for Medicaid recipients to get that transportation so they can receive necessary medical services covered by Medicaid.

How do I get non-emergency transportation services?
If you are a Medicaid recipient and have no other way to get to medical care or services covered by Medicaid, you can contact a transportation broker to take you. In most cases, you must call three days in advance to schedule transportation. Urgent care situations and a few other exceptions can be arranged more quickly. Each broker has a toll-free telephone number to schedule transportation services, and is available weekdays (Monday-Friday) from 7 a.m. to 6 p.m.. All counties in Georgia are grouped into five regions for NET services. A NET Broker covers each region. If you need NET services, **you must contact the NET Broker serving the county you live in** to ask for non-emergency transportation. See the chart below to determine which broker serves your county, and call the broker's telephone number for that region.

What if I have problems with a NET broker?
The Division of Medical Assistance (DMA) monitors the quality of the services brokers provide, handling consumer complaints and requiring periodic reports from the brokers. The state Department of Audits also performs on-site evaluations of the services provided by each broker. If you have a question, comment or complaint about a broker, **call the Member CIC toll free at 866-211-0950.**

Region	Broker / Phone number	Counties served
North	Southeastrans Toll free 1-866-388-9844 Local 678-510-4555	Banks, Barrow, Bartow, Catoosa, Chattooga, Cherokee, Cobb, Dade, Dawson, Douglas, Fannin, Floyd, Forsyth, Franklin, Gilmer, Gordon, Habersham, Hall, Haralson, Jackson, Lumpkin, Morgan, Murray, Paulding, Pickens, Polk, Rabun, Stephens, Towns, Union, Walker, Walton, White and Whitfield
Atlanta	Southeastrans Local 404-209-4000	Fulton, DeKalb and Gwinnett
Central	LogistiCare Toll free 1-888-224-7981	Baldwin, Bibb, Bleckley, Butts, Carroll, Clayton, Coweta, Dodge, Fayette, Heard, Henry, Jasper, Jones, Lamar, Laurens, Meriwether, Monroe, Newton, Pike, Putnam, Rockdale, Spalding, Telfair, Troup and Wilkinson

East	LogistiCare Toll free 1-888-224-7988	Appling, Bacon, Brantley, Bryan, Bulloch, Burke, Camden, Candler, Charlton, Chatham, Clarke, Columbia, Effingham, Elbert, Emanuel, Evans, Glascock, Glynn, Greene, Hancock, Hart, Jeff Davis, Jefferson, Jenkins, Johnson, Liberty, Lincoln, Long, Madison, McDuffie, McIntosh, Montgomery, Oconee, Oglethorpe, Pierce, Richmond, Screven, Taliaferro, Tattnall, Toombs, Treulen, Ware, Warren, Washington, Wayne, Wheeler and Wilkes
Southwest	LogistiCare Toll free 1-888-224-7985	Atkinson, Baker, Ben Hill, Berrien, Brooks, Calhoun, Chattahoochee, Clay, Clinch, Coffee, Colquitt, Cook, Crawford, Crisp, Decatur, Dooly, Dougherty, Early, Echols, Grady, Harris, Houston, Irwin, Lanier, Lee, Lowndes, Macon, Marion, Miller, Mitchell, Muscogee, Peach, Pilaski, Quitman, Randolph, Schley, Seminole, Stewart, Sumter, Talbot, Taylor, Terrell, Thomas, Tift, Turner, Upson, Webster, Wilcox and Worth

APPENDIX F

Georgia Families

Georgia Families (GF) is a statewide program designed to deliver health care services to members of Medicaid and PeachCare for Kids®. The program is a partnership between the Department of Community Health (DCH) and private Care Management Organizations (CMOs). By providing a choice of health plans, Georgia Families allows members to select a health care plan that fits their needs.

It is important to note that GF is a full-risk program; this means that the three CMOs licensed in Georgia to participate in GF are responsible and accept full financial risk for providing and authorizing covered services. This also means a greater focus on case and disease management with an emphasis on preventative care to improve individual health outcomes. In addition, each CMO may contract with a behavioral health or therapy service organization in order to coordinate physical and mental health services to improve member care, coordination, and efficiency.

Medicaid and PeachCare for Kids® members will continue to be eligible for the same services they receive through traditional Medicaid as well as new services. Members will not have to pay more than they paid for Medicaid co-payments or PeachCare for Kids® premiums. With a focus on health and wellness, the CMOs will provide members with health education and prevention programs as well as expanded access to plans and providers, giving them the tools needed to live healthier lives. Providers participating in Georgia Families will have the added assistance of the CMOs to educate members about accessing care, referrals to specialists, member benefits, and health and wellness education.

The Department of Community Health has contracted with three CMOs to provide these services: **Amerigroup Community Care, Peach State Health Plan and WellCare of Georgia**.

Members can contact Georgia Families at **www.georgia-families.com** or call **1-888-GA-ENROLL** (1-888-423-6765) for assistance to determine which program best fits their family's needs. If members do not select a plan, Georgia Families will select a health plan for them.

CMOs

Amerigroup Community Care	**Peach State Health Plan**	**WellCare of Georgia**
800-600-4441	800-704-1484	866-231-1821
www.myamerigroup.com	www.pshpgeorgia.com	www.wellcare.com

Children, pregnant women and women with breast or cervical cancer on Medicaid, as well as children enrolled in PeachCare for Kids® are eligible to participate in Georgia Families.

Georgia Families Regions

Region	Counties	Health Plans
Atlanta	Barrow, Bartow, Butts, Carroll, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Haralson, Henry, Jasper, Newton, Paulding, Pickens, Rockdale, Spalding, Walton	Amerigroup Community Care Peach State Health Plan WellCare of Georgia
Central	Baldwin, Bibb, Bleckley, Chattahoochee, Crawford, Crisp, Dodge, Dooly, Harris, Heard, Houston, Johnson, Jones, Lamar, Laurens, Macon, Marion, Meriwether, Monroe, Muscogee, Peach, Pike, Pulaski, Talbot, Taylor, Telfair, Treutlen, Troup, Twiggs, Upson, Wheeler, Wilcox, Wilkinson	Amerigroup Community Care Peach State Health Plan WellCare of Georgia
East	Burke, Columbia, Emanuel, Glascock, Greene, Hancock, Jefferson, Jenkins, Lincoln, McDuffie, Putnam, Richmond, Taliaferro, Warren, Washington, Wilkes	Amerigroup Community Care Peach State Health Plan WellCare of Georgia
North	Banks, Catoosa, Chattooga, Clarke, Dade, Dawson, Elbert, Fannin, Floyd, Franklin, Gilmer, Gordon, Habersham, Hall, Hart, Jackson, Lumpkin, Madison, Morgan, Murray, Oconee, Oglethorpe, Polk, Rabun, Stephens, Towns, Union, Walker, White, Whitfield	Amerigroup Community Care Peach State Health Plan WellCare of Georgia
Southeast	Appling, Bacon, Brantley, Bryan, Bulloch, Camden, Candler, Charlton, Chatham, Effingham, Evans, Glynn, Jeff Davis, Liberty, Long, McIntosh, Montgomery, Pierce, Screven, Tattnall, Toombs, Ware, Wayne	Amerigroup Community Care Peach State Health Plan WellCare of Georgia
Southwest	Atkinson, Baker, Ben Hill, Berrien, Brooks, Calhoun, Clay, Clinch, Coffee, Colquitt, Cook, Decatur, Dougherty, Early, Echols, Grady, Irwin, Lanier, Lee, Lowndes, Miller, Mitchell, Quitman, Randolph, Schley, Seminole, Stewart, Sumter, Terrell, Thomas, Tift, Turner, Webster, Worth	Amerigroup Community Care Peach State Health Plan WellCare of Georgia

Georgia Families Eligibility Categories

Included Populations	Excluded Populations
PeachCare for Kids®	**Nursing home**
Low-Income Medicaid (LIM)	**Federally Recognized Indian Tribe**
Right from the Start Medicaid (RSM)	**Georgia Pediatric Program (GAPP)**

Women's Health Medicaid (WHM)	Community Based Alternative for Youths (CBAY)
Transitional Medicaid	Children's Medical Services program
Refugees	Medicare Eligible
Planning for Healthy Babies	Supplemental Security Income (SSI) Medicaid Medically Needy
Resource Mother's Outreach	Long-term care
Children (Newborn)	
Breast and Cervical Cancer	

Included Categories of Eligibility:

COE	DESCRIPTION
104	LIM – Adult
105	LIM – Child
118	LIM – 1st Yr Trans Med Ast Adult
119	LIM – 1st Yr Trans Med Ast Child
120	LIM – 2nd Yr Trans Med Ast Adult
121	LIM – 2nd Yr Trans Med Ast Child
122	CS Adult 4 Month Extended
123	CS Child 4 Month Extended
126	Stepchild
135	Newborn Child
170	RSM Pregnant Women
171	RSM Child
194	RSM Expansion Pregnant Women
195	RSM Expansion Child < 1 Yr
196	RSM Expn Child w/DOB < = 10/1/83
197	RSM Preg Women Income < 185 FPL
245	BCC Waiver
471	RSM Child
506	Refugee (DMP) – Adult
507	Refugee (DMP) – Child
508	Post Ref Extended Med – Adult
509	Post Ref Extended Med – Child
510	Refugee MAO – Adult
511	Refugee MAO – Child
571	Refugee RSM - Child
595	Refugee RSM Exp. Child < 1
596	Refugee RSM Exp Child DOB </= 10/01/83
790	Peachcare < 150% FPL
791	Peachcare 150 – 200% FPL
792	Peachcare 201 – 235% FPL

793	Peachcare > 235% FPL
800	Presumptive BCC
804	Lim REI Adult
805	Lim REI Child
818	TMA REI Adult
819	TMA REI Child
835	Newborn
836	Newborn (DFACS)
871	RSM (DHACS)
872	RSM 150% Expansion (DHACS)
876	RSM Pregnant Women (DHACS)
894	RSM Exp Pregnant Women (DHACS)
895	RSM Exp Child < 1 (DHACS)
896	RSM Exp Child </= 10/01/83 (DHACS)
897	RSM Pregnant Women Income > 185% FPL (DHACS)
898	RSM Child < 1 Moth Aid = 897 (DHACS)
918	LIM Adult
919	LIM Child
920	Refugee Adult
921	Refugee Child

Excluded Categories of Eligibility:

COE	DESCRIPTION
124	Standard Filing Unit – Adult
125	Standard Filing Unit – Child
131	Child Welfare Foster Care
132	State Funded Adoption Assistance
147	Family Medically Needy Spend down
148	Pregnant Women Medical Needy Spend down
172	RSM 150% Expansion
177	Family Planning Waiver
180	Interconceptional Waiver
210	Nursing Home – Aged
211	Nursing Home – Blind
212	Nursing Home – Disabled
215	30 Day Hospital – Aged
216	30 Day Hospital – Blind
217	30 Day Hospital – Disabled
218	Protected Med/1972 Cola - Aged
219	Protected Med/1972 Cola – Blind
220	Protected Med/1972 Cola - Disabled

221	Disabled Widower 1984 Cola - Aged
222	Disabled Widower 1984 Cola – Blind
223	Disabled Widower 1984 Cola – Disabled
224	Pickle - Aged
225	Pickle – Blind
226	Pickle – Disabled
227	Disabled Adult Child - Aged
228	Disabled Adult Child – Blind
229	Disabled Adult Child – Disabled
230	Disabled Widower Age 50-59 – Aged
231	Disabled Widower Age 50-59 – Blind
232	Disabled Widower Age 50-59 – Disabled
233	Widower Age 60-64 – Aged
234	Widower Age 60-64 – Blind
235	Widower Age 60-64 – Disabled
236	3 Mo. Prior Medicaid – Aged
237	3 Mo. Prior Medicaid – Blind
238	3 Mo. Prior Medicaid – Disabled
239	Abd Med. Needy Defacto – Aged
240	Abd Med. Needy Defacto – Blind
241	Abd Med. Needy Defacto – Disabled
242	Abd Med Spend down – Aged
243	Abd Med Spend down – Blind
244	Abd Med Spend down – Disabled
246	Ticket to Work
247	Disabled Child – 1996
250	Deeming Waiver
251	Independent Waiver
252	Mental Retardation Waiver
253	Laurens Co. Waiver
254	HIV Waiver
255	Cystic Fibrosis Waiver
259	Community Care Waiver
280	Hospice – Aged
281	Hospice – Blind
282	Hospice – Disabled
283	LTC Med. Needy Defacto – Aged
284	LTC Med. Needy Defacto –Blind
285	LTC Med. Needy Defacto – Disabled
286	LTC Med. Needy Spend down – Aged

287	LTC Med. Needy Spend down – Blind
288	LTC Med. Needy Spend down – Disabled
289	Institutional Hospice – Aged
290	Institutional Hospice – Blind
291	Institutional Hospice – Disabled
301	SSI – Aged
302	SSI – Blind
303	SSI – Disabled
304	SSI Appeal – Aged
305	SSI Appeal – Blind
306	SSI Appeal – Disabled
307	SSI Work Continuance – Aged
308	SSI Work Continuance – Blind
309	SSI Work Continuance – Disabled
315	SSI Zebley Child
321	SSI E02 Month – Aged
322	SSI E02 Month – Blind
323	SSI E02 Month – Disabled
387	SSI Trans. Medicaid – Aged
388	SSI Trans. Medicaid – Blind
389	SSI Trans. Medicaid – Disabled
410	Nursing Home – Aged
411	Nursing Home – Blind
412	Nursing Home – Disabled
424	Pickle – Aged
425	Pickle – Blind
426	Pickle – Disabled
427	Disabled Adult Child – Aged
428	Disabled Adult Child – Blind
429	Disabled Adult Child – Disabled
445	N07 Child
446	Widower – Aged
447	Widower – Blind
448	Widower – Disabled
460	Qualified Medicare Beneficiary
466	Spec. Low Inc. Medicare Beneficiary
575	Refugee Med. Needy Spend down
660	Qualified Medicare Beneficiary
661	Spec. Low Income Medicare Beneficiary
662	Q11 Beneficiary
663	Q12 Beneficiary
664	Qua. Working Disabled Individual
815	Aged Inmate
817	Disabled Inmate
870	Emergency Alien – Adult

873	Emergency Alien – Child
874	Pregnant Adult Inmate
915	Aged MAO
916	Blind MAO
917	Disabled MAO
983	Aged Medically Needy
984	Blind Medically Needy
985	Disabled Medically Needy

HEALTH CARE PROVIDERS

For information regarding the participating health plans (enrollment, rates, and procedures), please call the numbers listed below.

Prior to providing services, you should contact the member's health plan to verify eligibility, PCP assignment and covered benefits. You should also contact the health plan to check prior authorizations and submit claims.

Amerigroup Community Care	Peach State Health Plan	WellCare of Georgia
800-454-3730 (general information) 888-821-1108 (provider recruitment) www.amerigroupcorp.com	866-874-0633 (general information) 866-874-0633 (claims) 800-704-1483 (medical management) www.pshpgeorgia.com	866-231-1821 www.wellcare.com

Registering immunizations with GRITS:

If you are a Vaccine for Children (VFC) provider, please continue to use the GRITS (Georgia Immunization Registry) system for all children, including those in Medicaid and PeachCare for Kids®, fee-for-service, and managed care.

Important tips for the provider to know/do when a member comes in:

Understanding the process for verifying eligibility is now more important than ever. You will need to determine if the patient is eligible for Medicaid/PeachCare for Kids® benefits and if they are enrolled in a Georgia Families health plan. Each plan sets its own medical management and referral processes. Members will have a new identification card and primary care provider assignment.

You may also contact Hewlett Packard (HP) at 1-800-766-4456 (statewide) or www.mmis.georgia.gov for information on a member's health plan.

Use of the Medicaid Management Information System (MMIS) web portal:
The call center and web portal will be able to provide you information about a member's Medicaid eligibility and health plan enrollment. HP will **not** be able to assist you with benefits, claims processing or prior approvals for members assigned to a Georgia Families health plan. You will need to contact the member's plan directly for this information.

Participating in a Georgia Families' health plan:
A Medicaid provider makes a business decision whether to participate in one, two or all three health plans. To participate in a health plan, the provider must be enrolled in Medicaid and sign a contract and be credentialed by the health plan. Each health plan has its own contracting procedures and

credentialing requirements. If a provider is interested in participating with a health plan, he/she should contact the plan's provider enrollment department.

Assignment of separate provider numbers by all of the health plans:

Each health plan will assign provider numbers, which will be different from the provider's Medicaid provider number and the numbers assigned by other health plans.

Billing the health plans for services provided:

For members who are in Georgia Families, you should file claims with the member's health plan.

If a claim is submitted to HP in error:

HP will deny the claim with a specific denial code. Prior to receiving this denial, you may go ahead and submit the claim to the member's health plan.

Receiving payment:

Claims should be submitted to the member's health plan. Each health plan has its own claims processing and you should consult the health plan about their payment procedures.

Health plans payment of clean claims:

Each health plan (and subcontractors) has its own claims processing and payment cycles. The claims processing and payment timeframes are as follows:

Amerigroup Community Care	**Peach State Health Plan**	**WellCare of Georgia**
Amerigroup runs claims cycles twice each week (on Monday and Thursday) for **clean** claims that have been adjudicated. **Monday** Claims run: Checks mailed on Tuesday. Providers enrolled in ERA/EFT receive the ACH on Thursday. **Thursday** Claims run: Checks mailed on Wednesday. Providers enrolled in ERA/EFT receive the ACH on Tuesday. **Dental:** Checks are mailed weekly on Thursday for **clean** claims. **Vision**: Checks are mailed weekly on Wednesday for **clean** claims (beginning June 7th) **Pharmacy:** Checks are mailed to pharmacies weekly on Friday (except when a holiday falls on Friday, then mailed the next business day).	Peach State has two weekly claims payment cycles per week that produces payments for **clean** claims to providers on Tuesday and Friday. For further information, please refer to the Peach State website, or the Peach State provider manual.	WellCare runs claims payment cycles up to six (6) times each week for **clean** claims. For further information, please refer to the WellCare website, the WellCare provider manual, or contact Customer Service at 866-231-1821.

How often can a patient change his/her PCP?

Amerigroup Community Care	Peach State Health Plan	WellCare of Georgia
Anytime	Within the first 90 days of a member's enrollment, he/she can change PCP monthly. If the member has been with the plan for 90 days or longer, the member can change PCPs once every six months. There are a few exclusions that apply and would warrant an immediate PCP change.	Anytime

Once the patient requests a PCP change, how long it takes for the new PCP to be assigned:

Amerigroup Community Care	Peach State Health Plan	WellCare of Georgia
Next business day	PCP changes are updated in Peach State's systems daily.	PCP changes made between the 1st and 10th of the month will go into effect right away. Changes made after the 10th of the month will take effect at the beginning of the next month.

PHARMACY

Georgia Families does provide pharmacy benefits to members. Check with the member's health plan about the who to call to find out more about enrolling to provide pharmacy benefits, including information about their plans reimbursement rates, specific benefits that are available, including prior approval requirements.

To request information about contracting with the health plans, you can call the CMOs provider enrollment services.

Amerigroup Community Care	Peach State Health Plan	WellCare of Georgia
888-821-1108	866-874-0633	866-231-1821
www.amerigroupcorp.com	www.pshpgeorgia.com	https://georgia.wellcare.com/

All providers must be enrolled as a Medicaid provider to be eligible to contract with a health plan to provide services to Georgia Families members.

The CMO Pharmacy Benefit Managers (PBM) and the Bin Numbers, Processor Control Numbers and Group Numbers are:

Health Plan	PBM	BIN #	PCN
Amerigroup	Caremark	610415	PCS
Peach State Health Plan	US Script	008019	Not Required
WellCare	CatamaranRx	603286	01410000

If a patient does not have an identification card:
Providers can check the enrollment status of Medicaid and PeachCare for Kids® members through HP by calling 1-800-766-4456 or going to the web portal at www.mmis.georgia.gov. HP will let you know if the member is eligible for services and the health plan they are enrolled in. You can contact the member's health plan to get the member's identification number.

Use of the member's Medicaid or PeachCare for Kids® identification number to file a pharmacy claim:

Amerigroup Community Care	Peach State Health Plan	WellCare of Georgia
No, you will need the member's health plan ID number	Yes	Yes

Health plans preferred drug list, prior authorization criteria, benefit design, and reimbursement rates:

Each health plan sets their own procedures, including preferred drug list, prior authorization criteria, benefit design, and reimbursement rates.

Will Medicaid cover prescriptions for members that the health plans do not?

No, Medicaid will not provide a "wrap-around" benefit for medications not covered or approved by the health plan. Each health plan will set its own processes for determining medical necessity and appeals.

Who to call to request a PA:

Amerigroup Community Care	Peach State Health Plan	WellCare of Georgia
1 (800) 454-3730, option 3, option 3	1 (866) 874-0633	1 (866) 269-5251 (phone) 1 (866) 455-6558 (fax)

APPENDIX G

Information for Providers Serving Medicaid Members
in the Georgia Families 360^{0} SM Program

Georgia Families 360^{0} SM, the state's new managed care program for children, youth, and young adults in Foster Care, children and youth receiving Adoption Assistance, as well as select youth in the juvenile justice system, launched Monday, March 3, 2014. Amerigroup Community Care is the single Care Management Organization (CMO) that will be managing this population.

DCH, Amerigroup, and partner agencies -- the Department of Human Services (DHS) and DHS' Division of Family and Children Services (DFCS), the Department of Juvenile Justice (DJJ) and the Department of Behavioral Health and Developmental Disabilities (DBHDD), as well as the Children's and Families Task Force continue their collaborative efforts to successfully rollout this new program.

Amerigroup is responsible through its provider network for coordinating all DFCS, DJJ required assessments and medically necessary services for children, youth and young adults who are eligible to participate in the Georgia Families 360^{0} SM Program. Amerigroup will coordinate all medical/dental/trauma assessments for youth upon entry into foster care or juvenile justice (and as required periodically).

Georgia Families 360^{0} SM members will also have a medical and dental home to promote consistency and continuity of care. Providers, foster parents, adoptive parents and other caregivers will be involved in the ongoing health care plans to ensure that the physical and behavioral health needs of these populations are met.

Electronic Health Records (EHRs) are being used to enhance effective delivery of care. The EHRs can be accessed by Amerigroup, physicians in the Amerigroup provider network, and DCH sister agencies, including the DFCS, regardless of where the child lives, even if the child experiences multiple placements.

Ombudsman and advocacy staff are in place at both DCH and Amerigroup to support caregivers and members, assisting them in navigating the health care system. Additionally, medication management will focus on appropriate monitoring of the use of psychotropic medications, to include ADD/ADHD medications.

Providers can obtain additional information by contacting the Provider Service Line at 1-800-454-3730 or by contacting their Provider Relations representative.

To learn more about DCH and its dedication to A Healthy Georgia, visit www.dch.georgia.gov

APPENDIX H

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